AIDS ISSUES
(Part 1)

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDREDTH CONGRESS

FIRST SESSION

MARCH 10, 1987—COST AND AVAILABILITY OF AZT
APRIL 27, 1987—AIDS AND MINORITIES
SEPTEMBER 22, 1987—AIDS RESEARCH AND EDUCATION

Serial No. 100-68

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AIDS ISSUES
Cost and Availability of AZT

TUESDAY, MARCH 10, 1987

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:55 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. The meeting of the subcommittee will come to order.

Last September the Department of Health and Human Services and the Burroughs Wellcome Company made a dramatic joint announcement. There was an AIDS drug. The drug AZT had been in clinical trials in humans for 7 months. The trials were double-blinded and placebo-controlled. That is, by secret random selection half of the patients received AZT and half received a placebo.

A few months later researchers began to report that some AIDS patients were clearly getting better. Others were dying. The researchers insisted that a scientific safety board break the secret code to see if the drug was producing these results.

In September the safety board revealed that about 1 out of 8 patients in the control group had died compared to one out of 145 of the patients receiving AZT. Given this information, both HHS and Burroughs Wellcome decided that it would be unethical to continue the study, that keeping some patients off the drug endangered their lives.

While formal approval procedures began, all control group patients were given AZT. In addition, Burroughs Wellcome and HHS began to supply AZT free of charge to any AIDS patient in America who had symptoms similar to those of the study. To date, over 4,500 patients have been given the drug.

In January the FDA's scientific advisory panel recommended that the drug be approved for sale in the U.S., England and France have already approved its sale. Last month Burroughs Wellcome announced that the drug will wholesale for about $7,000 per patient per year. The retail price is expected to be between $8,000 and $10,000.

There are a number of major questions that must be answered in today's hearing. Is this a fair price? Who will pay for the people who are now being treated for free? Who will pay for the people who become ill after the drug is approved? Who is responsible for people who cannot pay?

But the guiding principle in answering these questions has already been given by HHS and Burroughs Wellcome as part of their original dramatic announcement: Keeping AIDS patients off AZT endangers their lives. It would be unethical to do so.

We cannot permit the health care system to keep this drug away from people any more ethically than we could have permitted the health research system to do so. Giving patients sugar pills because they are part of a study can be justified as an effort to learn about a disease and its cure. Giving patients nothing because they have no insurance and no money can be rationalized only as a part of a system that provides health miracles to the wealthy and health neglect to the poor.

This subcommittee has wrestled with aspects of these problems before, perhaps most visibly in the question of paying for organ transplants and the expensive drugs that are needed to make them successful. Today we confront the problems in their most crystallized form. If the manufacturer, the States and the Federal Government work well, lives can be prolonged, perhaps for a long time, perhaps until a cure for AIDS is found. If we do not, poor AIDS patients will die. It's as simple as that.

Before calling on our witnesses, I want to recognize the distinguished ranking minority member of the subcommittee, Mr. Madigan.

Mr. MADIGAN. Thank you, Mr. Chairman. Mr. Chairman, this morning's hearing brings into focus once again the problem of meeting the high cost of providing health care with finite resources. The question is, "Who is going to pay for it? And it's a refrain which we have heard repeatedly in the past and which we will continue to hear in the future, not only with regard to this therapy but with regard to many others.

I hope that the witnesses today will help us in developing a rational answer to that question, and will not automatically say that, "It is not us who will be paying for it." The AZT therapy has been demonstrated to prolong the lives of certain AIDS patients. The question is—or the first question is, should it be made available to those patients at little or no cost? What if a superior drug is discovered, should it also be made available? Should the provision of AZT be continued if some superior drug is discovered? Those are just some of the questions.

I'm interested in the future prospects for AIDS therapy and hope that the witnesses will focus on their planning for the future, as well as the immediate problem of financing AZT therapy. And I would hope that all of the witnesses this morning will keep in mind that this subcommittee will be hearing about numerous health issues in coming weeks. I'm sure all the members of the subcommittee will join me in requesting that the AZT issue be put in perspective with those other issues, particularly the testimony from various department officials.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Just very briefly, Mr. Chairman. I certainly commend you for going forward with this hearing. There are really two issues that I think are particularly important.

One, I would like to see Congress to bring some certainty and some new integrity to the drug approval process. In some instances drugs are approved too fast; in other instances drugs are approved too slowly. I'm very interested in looking at the AZT pricing issue in conjunction with an overall examination of the drug approval process.

The other reason that I think your hearing is so important, Mr. Chairman, is that there will be billions of dollars involved in the development of new drugs against AIDS. The prospects are there for abuses and problems steming from these drugs. I think it's very important that we maintain vigorous oversight. This hearing is an important first step in that process, and I look forward to your testimony.

Mr. WAXMAN. Thank you, Mr. Wyden. Mr. Whittaker.

Mr. WHITTAKER. Nothing, thank you.

Mr. WAXMAN. Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman. I commend you for looking into this subject of how we can withstand the cost of providing hopefully some treatment and drugs for those people who now have a non-curable disease. One of the tragedies of the public health response to this epidemic in America is the non-traditional response which public health authorities have adopted.

Notwithstanding the epidemic in the country specifically, we do not today call on States to report and notify public health authorities when a person with the AIDS virus is found in the course of treatment by physicians. Reporting the existence of a communicable disease is a normal, routine process that strangely in the treatment of this disease is not now being followed. As to why, that remains a good question.

I hope that this subcommittee will hold hearings on the failure of the public health authorities in this Nation to adopt normal, routine practices that can hopefully minimize the transmissability of this fatal virus to other citizens in our community. One of the tragedies of this whole thing is that we don't know the number of people in this country today who may have a need for this drug or other drugs that may come along because we have not been following the routine, normal response of public health authorities when a new communicable disease comes along. Namely, to report it to public health authorities.

I would hope someday, Mr. Chairman, that you will find time on your agenda to hold hearings on this issue and others that are designed to develop a public health response whereby this Government and State governments around the country will treat this issue as a public health issue and stop treating it as a civil rights issue. Thank you very much.

Mr. WAXMAN. Thank you, Mr. Dannemeyer. We will be holding a number of hearings on a number of the ramifications of the AIDS epidemic throughout the year, but the one today is on this question of the cost of AZT.

[The statement of Hon. Terry Bruce follows:]

STATEMENT OF HON. TERRY BRUCE

Thank you Mr. Chairman for holding this hearing.

The spread of the AIDS virus has truly become a national concern—one that demands the awareness of every American. Programs aimed at eliminating the threat of AIDS demand the uncompromised support of every American. I strongly believe that we must redouble our effort to devise both a preventive measure to protect the uninfected population and move forward in providing hope for Americans who already have AIDS.

The development of the drug AZT holds out new hope for AIDS victims and their families. Preliminary tests indicate that AZT will retard the ravages of AIDS and permit many patients to resume productive lives.

Unfortunately, AZT is prohibitively expensive—an estimated cost of up to $10,000 per year for each patient using the drug. For AIDS patients whose resources have already been exhausted, AZT can realistically only offer hope in conjunction with Federal assistance. Medicaid, the health care provider for low-income Americans, may spend as much as $800 million this year on assistance to AIDS victims. If Medicaid were to provide its AIDS patients with AZT the bill could jump to $950 million in 1988. With the welcome life prolonging effects of AZT we can expect increasing Federal Government cost exposure through the Medicare program. The cost of providing AZT raises the question of how best can the Federal Government provide for victims of AIDS.

Mr. Chairman, I commend you for holding this hearing and I look forward to the witnesses' testimony.

Mr. Waxman. And for our first witness, we're pleased to recognize Mr. T.E. Haigler, Jr., president and chief executive officer, Burroughs Wellcome Company. We're delighted to have you with us. We'll make your statement part of the record in full. We'd like to ask you to present your testimony orally and to try to highlight the main points, trying to keep as close to 5 minutes as possible.

STATEMENT OF T.E. HAIGLER, JR., PRESIDENT AND CHIEF EXECUTIVE OFFICER, BURROUGHS WELLCOME CO.; ACCOMPANIED BY DAVID BARRY, VICE PRESIDENT, RESEARCH

Mr. Haigler. Thank you, Mr. Chairman, for the opportunity to appear before your committee. I am T.E. Haigler, Jr., president and chief executive officer of Burroughs Wellcome Co., located in Research Triangle Park, NC. With me today is Dr. David Barry, our vice president for research.

As you know, it was Burroughs Wellcome research that first identified AZT, now called RETROVIR, as being of potential value in the fight against AIDS. And it was Burroughs Wellcome, along with a number of outstanding government scientists and university investigators who conducted the study and development of this drug which has brought hope to AIDS sufferers everywhere.

We have submitted a formal statement and asked that it be made part of the record. I will attempt to briefly summarize that statement and then answer your committee's questions.

Eight months ago Dr. Barry appeared at a Congressional hearing on AIDS research before Congressman Weiss and yourself. I think it is fair to say that tremendous progress has been made since then. Today we have a drug that is in the review process and hopefully will be soon approved for use against the human immunodeficiency virus.

We have gone from making the quantities necessary for small scale clinical trials to a situation where more than one-third of all living AIDS patients in the United States are receiving RETROVIR therapy. Normally, it would take about 5 years to devise and perfect the production methods required to go from synthesizing small quantities of drugs to the tons currently being produced. Through an enormous effort, we have succeeded in increasing our supply more than a thousandfold in the last 18 months. We have invested millions of dollars in the research program that has brought this drug from the laboratory to more than 4,000 patients in a period of less than 3 years.

We began this research at a time when AIDS was not considered a significant public health problem by the general public. We did this because we felt our experience with antivirals would enable us to make a valuable contribution to the fight against this devastating disease, and we believed we had an obligation to do so.

This effort involved a significant of financial risk. The full usefulness of RETROVIR is unknown. Efficacy and speed of introduction of other therapies are unknown. Our financial returns are uncertain. After we showed that the antiviral approach could indeed by successful, others have taken an active interest in this therapeutic area. And we believe that that is in the public good.

The costs involved in this project have been significant. Apart from the millions of dollars that we have spent in research, Wellcome has committed more than $80 million in additional capital for raw materials for production of RETROVIR. This is above and beyond other usual costs associated with manufacturing and distributing RETROVIR to patients.

Mr. Chairman, as I am sure you and your committee know, despite our best efforts, we will be faced with the difficult situation of having a somewhat limited supply of RETROVIR initially following FDA approval. However, let me assure you that we are devoting the necessary time, technology, personnel, and financial resources to continually increase supply. I can say that the supply situation is constantly evolving and improving.

We expect to have adequate supplies of the drugs available for most seriously ill patients immediately upon approval. And Mr. Chairman, we expect our supply to be sufficient to meet the needs of more than 30,000 patients in the United States by the end of the year.

We have discussed an appropriate distribution system with the FDA and other agencies in the Department of Health and Human Services and outside experts. This distribution system will be in place at the time of FDA approval.

At this point, Mr. Chairman, I think we can safely say that drug therapy offers the only hope for patients suffering from this deadly disease. While education and ultimately vaccines may help to slow the acquisition of the virus, drug therapy is the modality that will have the most positive impact on the substantial population already infected. The hope of drug therapy is to save lives, return patients to productive lives, and keep patients with minimal symptoms healthy.

We have shown that RETROVIR can prolong life in those patients who have one of the most severe forms of human immunodeficiency disease. We know that RETROVIR can reduce their risk of opportunistic infections and improve their ability to live day to day.

On the health care expenditure side, we believe RETROVIR will reduce annual direct costs for the patient with advanced forms of the disease. We believe the RETROVIR therapy also will limit the progression of patients from less serious to more serious forms of the disease. Aside from the obvious benefits to the patient, this will also reduce health care costs. As we all know, the end stages of HIV infection are when the largest consumption of health care resources occur.

We estimate that the annual cost of RETROVIR to patients could be in the range of $7-to $10,000. Let me assure you that we have considered a number of factors in establishing our price for RETROVIR. We have considered the high cost of developing and producing this drug, and the very real needs of the patients for whom it was developed.

I believe we have balanced our concern for patients with the development and production costs involved and the risks we have assumed. We have recognized our need to recover our cost, achieve a financial return in an uncharted therapeutic area and in an uncharted, uncertain future.

It is my hope, Mr. Chairman, that the proceeding has been of value. Dr. Barry and I will be happy to answer any questions you might have.

[The prepared statement of Mr. Haigler follows:]

Statement of T.E. Haigler, Jr.

I am T.E. Haigler, Jr., president and chief executive officer of Burroughs Wellcome Co., a research-based pharmaceutical company located in Research Triangle Park, North Carolina. With me is David Barry, M.D., our vice president of research.

I am pleased to have the opportunity today to provide information about Burroughs Wellcome's efforts in the discovery and development of RETROVIR for the treatment of certain patients suffering from diseases associated with the human immunodeficiency virus, namely Acquired Immune Deficiency Syndrome (AIDS) and AIDS Related Complex (ARC). I would like to give you some background information about Burroughs Wellcome and its prior work in the antiviral area. I will then summarize our research and development efforts with respect to RETROVIR and describe our supply situation and distribution plans for RETROVIR, including pricing considerations.

BACKGROUND

Burroughs Wellcome is the American subsidiary of The Wellcome Foundation, Ltd., a worldwide group of pharmaceutical companies. The Wellcome enterprise was founded in 1880 by two American pharmacists, Silas Burroughs and Sir Henry Wellcome. Throughout the years, it has been dedicated to the advancement of medical knowledge and care. The Wellcome Foundation was established in 1924 to consolidate the international business of Wellcome.

In 1936, Sir Henry's will created the charitable Wellcome Trust as the Foundation's sole shareholder and directed that earnings would be used to further medical and scientific research to improve the physical condition of mankind. Since its creation, The Trust has distributed more than $180 million dollars to worldwide medical research, independent of Wellcome research activities, making it the largest private philanthropy in Great Britain.

In 1986, 25 percent of the Foundation shares were offered for public sale. The other 75 percent remain with the Trust. This public offering was intended to diversify the Trust's source of income and provide additional resources for its work. After 105 years, Wellcome became a publicly held company and now is traded on the London Exchange.

Burroughs Wellcome Co., the United States subsidiary, was founded in 1906. It employs more than 3,500 people in the United States and is dedicated to research, development, manufacturing and marketing of human pharmaceutical and diagnostic products. The company makes about 90 products including antibacterials, analgesics, and drugs to treat cardiovascular diseases, gout, malaria, cancer and organ transplant rejection. Seven of our medicines have been used in the treatment of various manifestations of AIDS and its associated opportunistic infections.

A particular area of interest and success at Wellcome has been the development of antiviral agents. Over three decades, Wellcome scientists have developed the most successful antiviral program in medical research. This research grew out of pioneering studies in cancer chemotherapy and nucleic acid derivatives in the 1940s and 1950s. It pointed the way to the company's first antiviral drug, MARBORAN, which was used during the 1960s for the prevention of smallpox and treatment of smallpox vaccination complications.

Burroughs Wellcome began an intensive research effort to discover new antiviral compounds in the 1960s and 1970s. The company developed VIROPTIC brand trifluridine to treat herpes infections of the eye and later discovered ZOVIRAX brand acyclovir, the first antiviral to selectively attack a virus while leaving normal cells virtually untouched. Intravenous ZOVIRAX and ZOVIRAX Ointment were introduced in 1982 for the treatment of initial genital herpes infections and herpes simplex infections in patients with inadequate immune systems. ZOVIRAX Capsules were introduced in 1985 and are used worldwide for the treatment and suppression of a variety of herpes group infections including genital and facial herpes as well as shingles. ZOVIRAX has helped millions of people in their efforts to deal with the medical and psychological effects of infections caused by this group of viruses.

RESEARCH AND DEVELOPMENT

Our research into AIDS is a natural extension of this antiviral program. This research began at a time when AIDS was not considered a significant public health problem by the general public, and pharmaceutical manufacturers generally did not consider the illness to be one involving significant financial rewards. We initiated this research because we felt that, based on our antiviral experience, we could make a valuable contribution to the fight against this devastating disease.

Our AIDS research program began in June 1984 with a study of chemical compounds which we felt might be effective against the AIDS virus. In November 1984 we identified a compound, AZT, also known as azidothymidine or zidovudine, and which we now call RETROVIR, which inhibited the replication of certain animal viruses in the laboratory. Independent laboratory testing in late 1984 and early 1985 confirmed that zidovudine was effective in inhibiting the multiplication of the human AIDS virus in the test tube.

Toxicologic and pharmacologic testing began in the spring of 1985, as did work on scaling up synthesis of the drug. On June 14, 1985, we submitted an application to the Food and Drug Administration to obtain an Investigational New Drug Exemption for the use of RETROVIR in humans. On June 21, 1985, the FDA indicated that the data were sufficient to allow us to begin clinical studies in humans.

The first patient received RETROVIR on July 3, 1985 at the Clinical Center of the National Institutes of Health. This initial Phase I study ultimately involved 35 patients. It showed that adverse reactions were limited, consisting primarily of some bone marrow suppression in some patients when taking high drug doses for prolonged periods of time. The study also indicated that RETROVIR was well absorbed after oral administration and entered the brain in reasonable amounts. Some of the patients showed some objective and subjective evidence of improvement, including an increased sense of well-being, weight gain, and improvement in various measures of their immune system.

These responses were sufficiently encouraging to allow us to begin a Phase II double-blinded, placebo-controlled study of RETROVIR.

This study, which took place at 12 medical centers throughout the country, began on February 18, 1986. It was financed solely by the Burroughs Wellcome Co. It began five months before the National Institute of Allergy and Infectious Diseases selected the AIDS Treatment and Evaluation Units (ATEUs). Most of the 12 centers involved in the Burroughs Wellcome study were eventually selected as ATEUs. A total of 282 AIDS and AIDS Related Complex (ARC) patients were enrolled in this study during the period of February to June 1986. Because of the ehical concerns raised by a placebo-controlled study in a uniformly fatal disease, arrangements were made to convene a Data and Safety Monitoring Board, through the auspices of the National Institute of Allergy and Infectious Disease, to examine the data on patients in the study every two to three months. If either the placebo or the drug-treated group did either so poorly or so well that it would be unethical to continue the study as designed, this outside review board would inform us and the study would be stopped.

In September 1986, an interim analysis presented to this board showed that there was a significantly lower mortality rate in patients randomized to receive RETROVIR compared to those randomized to receive placebo. The trial was halted. At the time the trial was stopped, there had been 16 deahts among the 137 patients receiving placebo and one death among the 145 patients receiving RETROVIR. The group receiving RETROVIR also had a decreased number of opportunistic infections. This was true of both AIDS and ARC patients. In addition, weight gain and improvements in the immune system and the ability to perform daily activities noted in the earlier study were confirmed in this larger study. Bone marrow suppression continued to be a significant side effect.

Because this study showed the benefits of RETROVIR therapy outweighed the risks associated with treatment in certain groups of AIDS and ARC patients, placebo recipients in this study were given the opportunity to receive RETROVIR therapy. Eighty-four percent of the patients enrolled in this study are alive today, more than one year after the first patient was enrolled. In addition, the National Institutes of Health, the Food and Drug Administration and Burroughs Wellcome established an investigational new drug (IND) program to make RETROVIR more widely available to the group of patients for whom the benefits had been shown overwhelmingly to outweigh the risks, namely AIDS patients who had recovered from at least one episode of pneumocystis carinii pneumonia.

Since September 1986, more than 4,500 patients, one-third of all living AIDS patients in the United States, have received RETROVIR free of charge from Burroughs Wellcome through this treatment IND program. There are 2,122 physicians registered with the treatment IND program and 919 registered pharmacists. We anticipate that the treatment IND program will ultimately distribute more than $10 million worth of drug.

While this program was being implemented, a U.S. New Drug Application (NDA) was filed in sequential segments with the FDA to ensure that the data were under review as rapidly as possible. The submission of the NDA began in October and was completed on December 2, 1986. The FDA held an advisory committee meeting to review the data on January 16 of this year. The committee voted 10 to 1 to recommend approval of RETROVIR for the treatment of most AIDS patients and certain seriously ill ARC patients. We have supplied the FDA with additional information they requested and are in active discussion with them, including meetings later today. We expect approval in the very near future. License applications have been submitted to a number of regulatory authorities in other countries by the Wellcome Foundation. Approvals for general sale already have been granted in the United Kingdom and France.

In the meantime, we have continued our efforts to learn more about RETROVIR and the patients for whom it might be beneficial. Our clinical trial program has expanded and we expect to begin studies with RETROVIR in 1,500–2,000 patients around the world within the next six months. This program will include pediatric patients, patients with Kaposi's sarcoma, neurological disease, ARC and asymptomatic infection. Also underway are studies to test the effectiveness of RETROVIR in combination with other drugs as well as its usefulness in patients undergoind bone marrow transplantation or T-lymphocyte transfusions.

These efforts are just part of a multimillion dollar investment in research which brought this drug to its current status in a period of less than three years. Currently, about one-fifth of all research and development spending at Burroughs Wellcome Co. involves RETROVIR. Clinical trials of drugs in AIDS and ARC patients are extraordinarily expensive because of the difficulty in culturing the virus, the relatively long-term nature of most human immunodeficiency virus (HIV) studies and the extremely complicated nature of the illness which these patients present to the clinician. We began this research at a time when the full impact of this disease was not fully appreciated and the chance of success was highly unlikely. This effort involved a significant amount of financial risk. Because the full usefulness of RETROVIR and the efficacy and speed of introduction of competitive products are unknown, our financial returns are uncertain. However, the research we have done has already contributed to a greater understanding of the disease. For example, the information collected from the placebo arm of our phase II trial alone is the most rigorous study of the natural history and progression of AIDS and ARC. The data will provide an excellent foundation for the research efforts of our own company and many others who have only recently begun taking a greater interest in this therapeutic area.

PRODUCTION AND SUPPLY

Parallel to our efforts to expand our clinical knowledge about RETROVIR have been our efforts to increase production of the drug so that it can be made more widely available to appropriate patients. Compared to most other drugs, RETROVIR is a complex and very expensive drug to manufacture. The overall process from original raw material to delivering RETROVIR to the patient takes about seven months.

The chemical production process can be divided into two sections. First, the work done externally to make and supply thymidine, a key raw ingredient, and then the work done by Burroughs Wellcome to go from raw material to final drug substance.

For our initial work on zidovudine, we purchased commerically available thymidine, which had been obtained as a side product from the DNA in salmon and herring sperm. We are informed that the annual worldwide usage, at this time, was about 25 pounds. By the summer of 1985, the world's available supply of thymidine had been exhausted. We, therefore, had to find companies with the appropriate technology to manufacture larger quantities of both natural and synthetic thymidine for us as fast as possible.

One company in particular, Pfizer Inc., has been very cooperative and allowed us to continue our development with minimal delays. They have a multi-step process which involves about 10 chemical reactions. Even with this technology, a great deal of work was involved to increase the world's supply of thymidine several thousand-fold in less than two years. The costs have been significant and were undertaken with no assurance during most of that period that a commerically viable product would result. Because of the complexity of the synthesis and the quantities involved, several chemical plants are involved in production of thymidine.

Burroughs Wellcome uses six chemical reactions in a series of stages to convert thymidine to RETROVIR. By employing the majority of our chemical development resources over the past 18 months, we have doubled the efficiency of these stages. Normally it would take about five years to devise and perfect the methods required to increase the amount of drug synthesized from the fraction of an ounce produced for initial study to the tons needed for availability to thousands of patients. Through improvements in technology, the cooperation of our suppliers and our willingness to disrupt production plans, we have been successful in increasing our supply by a factor of 10 every six months for the past year and a half.

The costs involved in this operation have been significant. The Wellcome group has committed more than $80 million in additional capital and raw material specific to RETROVIR. This is above and beyond other usual costs associated with manufacturing and distributing RETROVIR to patients.

Despite our best efforts, however, we will be faced with the difficult situation of having a somewhat limited supply of RETROVIR for a period of time in the near future. We are devoting the necessary time, technology, personnel, and financial resources to continually increase supply. The supply situation is constantly evolving and improving. We believe that adequate supplies of RETROVIR will be available for the most seriously ill patients immediately, and project that supplies for a minimum of 30,000 patients and probably more will be available by the end of 1987.

However, because of the limited availability of RETROVIR initially following FDA approval, there appears to be a need for some type of controlled distribution system. Burroughs Wellcome has discussed an appropriate system with the FDA and other agencies in the Department of Health and Human Services. A panel of experts, chaired by Dr. Sheldon Wolff and organized through the auspices of the Infectious Disease Society of America, is serving as an outside consultant to help us with this system. These groups and the FDA Advisory Committee understand our supply situation and the proposed distribution system and have indicated their support of our plans.

The company has three goals in distributing the available supply of RETROVIR. We have a commitment to help ensure the continued availability of this medicine to patients who already have begun RETROVIR therapy, as long as the drug is medically appropriate for them. We want to channel the available supply to the patients with the greatest need and those patients who are most likely to benefit from RETROVIR therapy, given our present state of knowledge about the drug. We need to ensure an adequate supply to meet their continuing needs. In addition, we have to set aside enough drug to continue a large clinical trial program in order to advance our knowledge about RETROVIR therapy and further identify the patients for whom it may be beneficial. A distribution system designed to meet these objectives will be in place when the drug is approved.

The system will be similar to the process presently being followed in the treatment IND program. During the period of limited drug supply, criteria for patient selection will be determined based upon the indications in our FDA-approved package insert and in consultation with our outside experts. Physicians will apply for the drug on behalf of individual patients. Qualified patients with a physician's prescription will be given an identification number and RETROVIR will be shipped directly from Burroughs Wellcome to a pharmacy of the patient's choice. This system will enable us to alert physicians as soon as additional drug supplies become available.

The price Burroughs Wellcome will charge wholesalers for RETROVIR is expected to be $188 per bottle of 100, 100 mg capsules. The monthly and yearly cost for individual patients will vary depending on dosage regimens and length of time on therapy, as well as distribution costs. We estimate that the annual retail cost of RETROVIR therapy for a patient could be in the range of $7,000 to $10,000. We are informed that the price Wellcome companies will charge for RETROVIR will be consistent throughout the world.

In arriving at the price for RETROVIR, we looked at the usual factors that influence pricing decisions. These include the costs of developing, producing and marketing the drug, the high costs of research, and the need to generate revenues to cover these continuing costs. Other factors considered include the uncertain market for the drug, the possible advent of new therapies, and profit margins customarily generated by significant new medicines. We also examined factors that might be considered to be unique with respect to RETROVIR. These included the very high cost of producing this drug and the very real needs of the patients for whom this drug was developed.

We considered all of these factors and attempted to arrive at a price that we considered reasonable. However, the cost to the patient will be relatively high for all the reasons I have described.

This situation is particularly difficult when one realizes that the clinical improvements achieved through RETROVIR therapy may make disabled patients productive citizens but at the same time disqualify them fromeligibility in health care safety net programs. Also, a very substantial portion of the money they earn when re-entering the workforce may have to be spent on the medicine that has enabled them to return to work.

As part of our regular procedures, Burroughs Wellcome Co. maintains a limited indigent care program for some of its life-saving therapies. These patient requests are considered on a case-by-case basis. We hope to continue this with RETROVIR, but the magnitude of the potential need and the impact of the illness are so enormous that we know it is beyond our scope.

In our view, it is a national public health problem well beyond the resources of one company, and must be dealt with by governments, employers and the health insurance industry.

COST-EFFECTIVENESS

An important aspect of RETROVIR therapy is that it appears to substantially lower the present costs of treating AIDS patients are limited, analysis of the available data for RETROVIR indicates that RETROVIR therapy is extremely cost-effecitve. One study done in San Francisco estimates that the cost of treating AIDS patients for one year is approximately $43,500. Other estimates place the cost at a substantially higher figure, some as high as $150,000 per patient. Analysis of the data presently available, using the lower San Francisco base line, indicates that treating AIDS patients with RETROVIR could reduce direct medical costs during the first year by about 25 percent. It is anticipated that the cost of treating ARC patients could be reduced by about 60 percent in the first year, primarily because of fewer opportunistic infections and fewer hospitalizations. Projecting these savings to a population of 20,000 AIDS and ARC patients treated with RETROVIR indicates a combined first year savings of $386 million.

There are also large indirect costs associated with HIV-related conditions, including AIDS. Some of these indirect costs are the loss of wages for sick persons, the loss of future earnings for persons who are permanently incapacitated or die because of illness, and the cost of infection control in the course of other health services, such as dental care. The Centers for Disease Control estimate that the first 10,000 patients with AIDS lost approximately 8,387 years of work and $189 million in potential earnings due to disability. The economic loss from future earnings lost following premature death are calculated to be $4.6 billion. (Ann M. Hardy, DPH, et al., *Journal of the American Medial Association*, January 10, 1986.)

In addition, it is possible that RETROVIR therapy may affect the progression of patients from less serious to more serious forms of the disease, further reducing health care costs. More important than the cost savings is the evidence that RETROVIR can prolong life in certain patients as well as improve the quality of that life. Data from our multi-center trial indicates that 68 percent of the AIDS patients treated with RETROVIR were able to continue or resume productive lives. In addition, a recent study by scientists at the National Cancer Institute published in *The Lancet* suggests that RETROVIR may reverse some of the dementia and other neurological disorders in some patients with HIV infections. We have similar data from our own multi-center study. While a great deal more research needs to be done in this area, the observation that RETROVIR may modify the neurological impact of this disease has significant implications for patients and their future outlook.

As a research-intensive pharmaceutical company, Burroughs Wellcome Co. has focused its efforts on what we do best—discovering and bringing new drugs to market. As we determined the price of the drug, however, we alerted those responsible for public and private policy and financing to the difficulties that some patients might face in purchasing the drug.

We are concentrating on the scientific and technical challenges of discovering and bringing to market the first effective therapy for AIDS. But we hope we have not lost sight of the patients and their families. Their need has been an ever-present reality to us, and their improvement on RETROVIR therapy has provided us with the encouragement to continue our efforts.

Our concern for patients has led us to make a number of other commitments as well. Our interest in providing and acquiring information will not end when the drug is commercially available. We will continue to support and participate in educational efforts in the United States and around the world to advance the state of knowledge about AIDS therapy. We will broaden our discussions to include state governments by assisting in the development and and dissemination of a policy guide for states on AIDS issues. We will have a significant educational effort designed for physicians and other health care providers to help assure they are well-informed about RETROVIR therapy and its role in the management of human immunodeficiency virus diseases. Our medical department will be doing follow-up studies on patients who are already receiving RETROVIR and initiating studies in many other important patient sub-groups.

Burroughs Wellcome has succeeded in rapidly developing the first drug to provide hope to patients who formerly were faced with almost certain death. We have conducted, and will conduct, clinical trials that add significantly to medical understanding of AIDS and ARC as disease conditions. For now, drug therapy offers the only hope for patients with this disease. While education and, ultimately, vaccines may help to slow the acquisition of the virus, drug therapy is the modality that will have the most positive impact on the substantial population already infected.

Mr. Chairman, this concludes my remarks. I will be happy to answer any questions you may have and hope I can be of assistance to you and others as you deal with this important topic.

Mr. WAXMAN. Thank you very much, Mr. Haigler. Before we begin questions, let me say that I think that Burroughs Wellcome has done an outstanding job in getting this drug developed. I recognize that you've taken risks, that despite all your expenses this drug could become outdated quickly. The country has entrusted the essential function of making pharmaceuticals to the private sector companies and you have made it work. You're to be commended for it.

Mr. HAIGLER. Thank you, Mr. Chairman.

Mr. WAXMAN. You should have a fair return on your investment and fair compensation for the risks that you are taking with this product, and I understand the pharmaceutical manufacturers are not charitable businesses. But I also believe that pharmaceutical companies share with the public sector the responsibility of not just getting the drug on the market, but also getting it to patients. In this life and death situation, the responsibility is especially high.

I want to congratulate you on your development work and I look forward to working with you in getting AZT to people who need it. And let me proceed with my questioning in that spirit.

Mr. HAIGLER. Thank you, Mr. Chairman.

Mr. WAXMAN. The first issue I want to just discuss with you is the price for the drug. It's quite a high price. I gather the estimate is maybe $8,000 to $10,000 per patient per year. Now we're going to have to decide if a patient can pay for a drug with a cost tag on it of that magnitude. If the patient can't, will insurance pay for it? If insurance is not available, will government pay for it? And if no one can afford it, what will happen? These are questions that policymakers must grapple with.

But I want to discuss with you how you've come to the price that you now put on the drug. You want to recoup your investment. I want to ask you some questions about the investment that you've made in developing this drug.

As I look at the timetable, Burroughs Wellcome has done about a year of screening for drugs and 7 months of clinical trials involving only a few hundred people, as opposed to the thousands that are usually required. You've also received orphan drug status for AZT which should contribute as much as a 72 percent tax subsidy of your clinical costs. And in addition to that, you get a 25 percent tax credit for increased research and development.

After taxes, how much do you estimate that it cost to get AZT to the point of manufacture?

Mr. HAIGLER. You have asked a lot of questions there, Mr. Chairman, and I think first, if I might, in arriving at our price for RETROVIR, we looked at all of the usual factors that go into—that influence drug-pricing decisions. These certainly include, as you said, the cost of research—perhaps I can ask Dr. Barry in a minute to address that, the particular question about the short time—the cost of development of the drug, the cost of production of the drug, which includes certainly material costs, which in those cases are a fairly high cost, labor, overhead, yields that come about out of the process itself, waste management, capital expenditure cost, cost of distribution, medical information cost; all of these factors are usual factors in arriving at a drug-pricing decision.

Certainly other factors that we considered included the risk related to, as I think you said, the uncertainties of the market, the uncertainties about the full usefulness of RETROVIR, the possible advent of new therapy.

We also, I think, carefully considered two factors that are specific to RETROVIR, and that is the high cost of producing this particular drug, and the needs of those patients for whom this drug was developed.

Mr. WAXMAN. Let's go back to that first part, the cost of the development, research and development of the drug itself. You did have a quick timeframe for getting this drug to FDA, for which you are to be commended. It's essential that we get this drug out there as fast as possible.

On the other hand, the shorter period of time and the fewer number of patients involved meant there was less cost to you. And, of course, with some of the costs you incur, you get tax credits. It was considered an orphan drug because the number of people affected by the disease at the time you were seeking to get this drug approved put it in the category of an orphan drug benefiting a rare number of people or relatively small number of people who are affected, even though potentially we have large numbers of people that may have a need for this drug. You got a tax credit for that, you got a tax credit, 25 percent tax credit for the R&D costs.

Do you have a figure that you could give us after you take the tax credits as to how much it cost to do research and development to get the point of manufacture of the drug? We'll talk about the manufacturing costs in a minute.

Mr. HAIGLER. Mr. Chairman, I think all of those are very good questions, and in regards to the cost of research and development, perhaps I could ask Dr. Barry, who is certainly much more intimately familiar with that part of our process, to discuss this.

Mr. BARRY. Thank you.

The cost, particularly of the clinical trials, is not less than the cost of most—the development of most other drugs, for several reasons:

First, patients with AIDS and AIDS-Related Complex, so-called ARC, are not only extraordinarily ill, but have a multitude of infections which require a great deal of attention by the physician and many diagnostic procedures.

Mr. WAXMAN. Why don't you start by telling me what the costs were, and then we can compare them to other drugs.

Mr. BARRY. I really honestly don't have that cost figure, because it's difficult to differentiate from our entire research and development program, particularly in the antiviral area. But I did want to emphasize that although the number of patients were relatively small compared to the thousands of patients that are often examined in clinical trials, the expense in the relative term was not significantly less from other studies; first, as I mentioned, because of the extraordinarily difficult and complex medical care that must be given to the patients; second, because of the costs of the drug itself; and third, because these patients, as part of their clinical trial, must be cultured on a regular basis. And the cost of culturing——

Mr. WAXMAN. I want to stop you there, if you don't have a figure, and I understand it involves a lot of other considerations and other costs that you can't quite differentiate with this drug. But what you want to do, and you are entitled to, is recoup your investment. And you say that the pricing structure includes revenues to cover your development costs. If just the 4,500 patients that are now getting AZT continue, your income this year, when you are approved, would be $45 million. By the end of this year, there will probably be about 25,000 living AIDS patients in the United States. If all of them take AZT, your income next year would be about $250 million.

Most epidemiologists suggest that there are 10 times the number of people with ARC who have AIDS, so if FDA approved AZT for ARC, your income next year could be almost $3 billion. When you have all these series of projections, at some point you are going to recover your development costs, and we'd like to know after you do so—I expect there would be some decrease in the price of the drug—whether that would be realistic.

Let me put this in the context of Barron's publication which predicted profits of $200–$300 million this year. Do you agree with that estimate?

Mr. HAIGLER. I'm sorry; who?

Mr. WAXMAN. Barron's Magazine. Barron's has an article on the profits Burroughs-Wellcome can expect on AZT. I haven't seen this article, but I'm told that Barron's predicts profits of $200 to $300 million this year. Is that an estimate you would agree with?

Mr. HAIGLER. I don't have any basis—I don't know the basis of the estimate that they arrived at. So I really can't comment on that. But, no.

Mr. WAXMAN. You don't agree with that figure?

Mr. HAIGLER. No.

Mr. WAXMAN. One pharmaceutical company——

Mr. HAIGLER. I think, as I said earlier, if I may, Mr. Chairman, there are still a lot of uncertainties about this particular drug.

Mr. WAXMAN. I understand that, but I'm trying now to figure out the one component of recovering your investment, the development of this drug, and it looks like you have the potential to recover it many, manyfold. Now that shouldn't be the only basis for setting a price, I understand that. One pharmaceutical newsletter suggested that your mark-up of AZT is 100 percent, that half the price is going to be profit. Do you agree with that statement?

Mr. HAIGLER. I'm sorry, I can't respond to that, Mr. Chairman. I think, to go back to what I said earlier, the potentials of this drug may be there, but what will actually happen when the drug is finally approved and it's on the market, what those sales will be, we have no way of really knowing. We certainly don't know what's going to happen in the next year or two as far as new therapies are concerned. Whether this drug will continue to be the drug of choice and really used, we don't know. So I don't think we can speculate on what sales we will have or what profits we might see.

Mr. WAXMAN. You set the price of $8000 to $10,000 for the sale of the drug this year to reflect your investment, the uncertainties, and the profit potential, and you are not sure of the full profit potential, although it could be enormous, but I assume you're looking at the possibility it might not be as high as some people are conjecturing.

Now what price are you going to charge overseas for this?

Mr. HAIGLER. It's my understanding that the price overseas will relate specifically to our price here. There are exchange rate complications to get into that, but the base price will be, as I understand it from our parent company, will be the same in dollars as we are charging here.

Mr. WAXMAN. And have other countries agreed to this price?

Mr. HAIGLER. I do not know the answer to that, Mr. Chairman.

Mr. WAXMAN. Let me just move on to one other area that I want to examine with you, and that's the very unusual situation we have with this drug, because ethically you can't give a placebo any more, since we have a drug that we know will prolong the life of the patient. To try to establish whether another drug is going to be effective to deal with AIDS, a control drug has to be AZT.

In other words, before your competitors can get on the market, they have to be able to have access to AZT to use as the control drug by which they will measure their new chemical entity.

In order for anyone to do research on new, better, and cheaper AIDS drugs, they really need to have AZT to compare against.

I would like to know whether you will supply NIH with the AZT they need for research on other drugs, and will you supply it to your competitors?

Mr. HAIGLER. I'll ask Mr. Barry to respond to that.

Mr. BARRY. Yes, Mr. Chairman, we will. I think it should be pointed out, though, that your statement that AZT has to be a comparative drug for all patients with AIDS or AIDS-Related Complex may not necessarily be true. I think it would be true in studying those forms of the illness where the patients are extremely ill, and have a very poor prognosis. I think for milder forms of disease where we, as well as others, are still in the process of establishing the effectiveness of the drug, one would not necessarily compare with our drug.

Now in terms of working with the National Institutes of Allergy and Infectious Diseases, and the AIDS Treatment and Evaluation Units, we already have made a significant amount of drug available to them for studies and, in fact, four of the studies that are going on through those units are studies of AZT.

We have already said that in working with comparative drugs, that we would be working hand in hand with them, and we would be helping develop the protocols and review the various comparative therapies that would be done.

Mr. WAXMAN. I understand the drug that has been made available to NIH has been for the question of determining what the dosage of the AZT should be. Have you provided AZT to NIH researchers so that they can use that as a basis to compare competitor drugs?

Mr. BARRY. We have supplied it both to look at dosages, we have supplied it for pediatric study, to determine the effectiveness of the drug in pediatrics, and we are in the process of initiating a study in neurologic disease through the NIAID.

In terms of comparison with competitor drugs, to my knowledge, there is no competitor drug available now that has shown the effectiveness of AZT in prior studies. I'm not clear what you're referring to there. A comparative study between AZT and something else?

Mr. WAXMAN. Some other pharmaceutical.

Mr. BARRY. In terms of a straight comparison like that, we have not——

Mr. WAXMAN. Well, has NIH requested——

Mr. BARRY. Drug for comparative study against something else? Not to my knowledge. I think the question has come up as to whether AZT could be used in conjunction with some other competitor's drugs, and we have—we are in the process of making that drug available for combination studies with AZT alone, versus AZT in combination with other compounds, including acyclovir, including interferon, including a number of other potential therapies, and those discussions are ongoing. And what we have indicated is that if we see the data on other drugs that could be used in conjunction with AZT and the data appear to be valid and there is good reason to do the studies, we would go ahead and do them. But right now, with a limited supply, we cannot give a free and open supply to anyone who wishes to study our drug in conjunction with theirs. We have to make sure that the drug is being used properly.

Mr. WAXMAN. So you are in the anomalous situation, with a scarcity of this drug, that you're deciding the allocation of it. And, for research purposes, you're in the position to decide to approve an application for another drug where someone wishes to use AZT for comparison purposes, which would be the only basis they could go through their drug approval process. It would have to be approved by you, but you have not been requested by either NIH or any other drug company to make AZT available for that purpose. Is that your testimony?

Mr. BARRY. No, we have been requested by a number of groups, literally almost in the hundreds, to use our drug in combination to use our drug in connection with their particular therapy. What we have said is that we would make it available provided that the data that they have were valid in terms of giving a reason to use them together. And we have been in very active discussions about this as recently as 1 week ago——

Mr. WAXMAN. None has been agreed to yet?

Mr. BARRY. We agreed to one as recently as 1 week ago, in terms of a study with AZT and interferon. Now, in terms of that—I might add also, that's not the only way——

Mr. WAXMAN. I'm going to have to ask you to respond to my question. You approved one last week. In terms of approving another experiment like this, is it in NIH's purview to make the determination, or is it in your purview to make the determination whether an experiment would be reasonable or not under the criteria you have discussed as the basis for allowing the drug to be used?

Mr. BARRY. It would be under both of our purview. We will continue to work, as we have in the past, to ensure that the clinical studies are being performed properly and in agreement, much as we have worked with NIAID for many years.

I will point out, however, that this is being done at a time when we have an extremely limited drug supply. It is not the only way the drug would be obtainable after approval. And certainly there would be very easy mechanisms, if someone wanted to compare our drug in conjunction with theirs, or in contrast with theirs.

Mr. WAXMAN. Well, even if the drug were approved——

Mr. BARRY. After approval.

Mr. WAXMAN. Even if the drug were approved next week, there still wouldn't be a sufficient supply, so the supply would be controlled by some allocation system that you would determine?

Mr. BARRY. That is correct. There is a relatively limited supply, but as Mr. Haigler pointed out, that supply is increasing, and the precise supply is in an evolving situation, but I expect that it will loosen up a great deal. And as Mr. Haigler also mentioned, by the end of the year, we should have sufficient drug for over 30,000 patients in the United States alone.

Mr. WAXMAN. And the first priority is for those who otherwise would die?

Mr. BARRY. The first priority is for those patients who have been shown to benefit by the drug. I will point out, however, that we have set aside a very significant amount of drug for clinical trials.

Mr. WAXMAN. Thank you.

Mr. Madigan.

Mr. MADIGAN. If I can ask you, Mr. Haigler, I'd like to try to go back for just a moment and put the AIDS problem in a bit of an international perspective.

I have recently been told that 9 percent of the total population on the African Continent now tests positive to AIDS antibodies. Is that consistent with information that you have?

Mr. Barry. I think that's an estimate based on sampling of populations that may or may not be representative. But there is certainly a very large number of patients in Africa who are antibody-positive, but I don't believe anyone knows what that percentage is.

Mr. Madigan. And that the rate of this progressing through the heterosexual population on the African Continent is now roughly equal to the rate of progression in the homosexual population in the United States; is that correct?

Mr. Barry. From the best, and at times very rough, estimates that we have, that is correct.

Mr. Madigan. When this first became a matter of public concern in the United States in the 1981–1982 timeframe, we would read that approximately 10 percent of the people who tested positive to the presence of the antibodies would subsequently acquire the disease. I am now told that that conversion rate is more in the range of 90 percent. Is that also a correct estimate?

Mr. Barry. It's certainly above 10 percent. I would really defer to the epidemiologists, particularly from the Centers for Disease Control, that have been looking at this to see how much above 10 percent that is, and over what period of time.

Mr. Madigan. But with the passage of time, what we are finding is that the people who test positive to the presence of the antibodies with the passage of time, and because of the incubation period, a greater percentage than was originally projected are actually acquiring frank AIDS; is that not fair?

Mr. Barry. That appears to be the case.

Mr. Madigan. On page 4 of Mr. Haigler's testimony, it says, "Some of the patients showed some objective and subjective evidence of improvement, including an increased sense of well-being, weight gain, and improvement in various measures of their immune system."

I have heard of a particular case in Chicago where one of the patients has actually been able to go out and go back to work. Has that happened in more than one instance?

Mr. Barry. Yes, that's happened with a number of others.

Mr. Madigan. Is there any evidence yet as to whether or not AZT affects the ability of a person to transmit or communicate the AIDS disease?

Mr. Barry. No, there are no data to support that. What we have found in clinical studies is that evidence of viral multiplication within the body diminishes greatly when the patient is on the drug, as manifested by what's called the P-24 core antigen circulating the body. However, the amount of virus in the body, which is often in a so-called latent or non-replicating state is not decreased, because the drug is effective only against multiplying viruses. So if one removes blood cells from patients who are on therapy, one can still recover virus from them.

Mr. Madigan. With regard to our own blood supply in the United States, I'm told that in going back now and testing this blood supply, some contamination is found in blood going all the way back to blood donated in 1977. Does that concur with what you understand to be the case?

Mr. BARRY. Again, I'm not an expert in this area, but my understanding that the beginning of detection of virus in the American population in a very small number of patients did date from around that period.

Mr. MADIGAN. So it's possible for people to be AIDS patients today who are not homosexual, not intravenous drug users, but are merely people who at some point in time in the last 10 years were transfused; is that correct?

Mr. BARRY. That is correct.

Mr. MADIGAN. There is an ethical question, it seems to me, in determining priorities for the distribution of this drug. Since one group of potential recipients has a greater potential for the transmission of the disease than other groups, has there been any discussion of that ethical question within your company or between your company and health officials in the United States?

Mr. BARRY. I'm sorry, I'm not sure what you mean by some patients having a higher potential for transmitting the virus.

Mr. MADIGAN. If a homosexual patient gains weight, has an increased sense of well-being, improvement in various measures of the immune system, and as you have testified, is able to go out and go back to work, doesn't that person have a greater capacity for transmitting the disease than someone who has the disease as a result of having received a blood transfusion?

Mr. BARRY. Not to my knowledge, because the amount of virus that patients have varies tremendously. It does not appear to be necessarily related to how they acquired it—certainly not be blood transfusion. There is some evidence that patients who are hemophiliacs may have less virus than other patient populations. But there is no question that many asymptomatic patients have a very large amount of virus.

I'm not quite sure of your question.

Mr. MADIGAN. If one person has acquired the disease as a result of a blood transfusion and another as a consequence of sexual habits, is one more likely to refrain from sexual activity than the other?

Mr. BARRY. I'm really not an expert in that area, and I just don't know.

Mr. MADIGAN. I'm not questioning whether or not you're an expert. I'm questioning whether or not there has been any discussion of this within your company or between your company and U.S. health officials.

Mr. BARRY. The only discussion we've had has been with academic experts looking at the ability to culture virus from hemophiliacs versus non-hemophiliacs. But in terms of the question you've asked, it hasn't even been in that context, no.

Mr. MADIGAN. Two final questions. Is the present cost of this therapy comparable to the present cost for other types of therapies, such as the use of immunosuppressive drugs for organ transplants? Cyclosporin, for example.

Mr. BARRY. It's roughly comparable, but I don't have a precise number.

Mr. MADIGAN. And finally, can you tell me how many other companies here and internationally are engaged presently in research and development activities on a drug similar to AZT? Do you have any information on that?

Mr. BARRY. I don't have the precise number. I believe the Pharmaceutical Manufacturers Association is gathering data along those lines. Certainly, there are a very large number of companies who are working both on the chemotherapy of acquired immunodeficiency syndrome, as well as the diagnosis and prevention of that disease. It would be in the 20 to 50 to higher range, depending on how broad one wants to be in defining what research is in that area.

Mr. MADIGAN. And that would not include organizations like the Pasteur Institute in Paris, for example? These would only be proprietary companies that you're giving us a count on?

Mr. BARRY. Obviously the Pasteur Institute is working on it, but a very substantial of private pharmaceutical companies are also working in this area.

Mr. MADIGAN. I have no other questions.

Mr. WAXMAN. Thank you, Mr. Madigan. Mr. Wyden, it's your time, but I'd like to ask you if you'd yield to ask one question.

Mr. WYDEN. I'd be happy to yield to the chairman.

Mr. WAXMAN. The ability to transmit the disease is not related to the source of infection. A likelihood to transmit or resume sexual activity obviously depends on the individual, the counseling that individual might have had, and the education about transmission. Isn't that a correct statement?

Mr. BARRY. Yes.

Mr. WYDEN. Thank you, Mr. Chairman. If I might start back on the point the chairman made with respect to pricing. I think your comments established that there was a lot of uncertainty about how much it would cost the company to develop the drug and how much you might make on it. The profit picture in your mind was uncertain.

My question to you then is, did the company set the price randomly? How did the company set the price?

Mr. HAIGLER. Mr. Wyden, if I may, in arriving at the price, as I said, we looked at all of those factors of cost we knew at the time, what is was developing into in term of the research and development and production cost, what it seemed it was going to cost us to distribute the drug, taking into account the substantial financial investment that we had made.

And the price was not randomly set. It was set very carefully taking into account all of those factors. The fact that we need to generate revenues to support continuing research on this and other drugs. And at the same time taking into account the needs of the patients.

Mr. WYDEN. Did Burroughs think about——

Mr. HAIGLER. We just didn't pick a number out of the air.

Mr. WYDEN. Did Burroughs think of the number of Americans who are capable of paying for the drugs, when it set the price. I haven't heard you mention that? In setting the cost of AZT did the company think about all the people who can't pay. Did they factor that into the pricing structure?

Mr. Haigler. Certainly the cost of the drug was—the price of the drug itself, as I said, was determined considering a lot of factors. I think it's important to remember that drug therapy is just one element in the cost of treating AIDS. And as we said and stated, RETROVIR therapy does appear to substantially lower the present cost of treating AIDS patients.

So we think that the drug will be cost effective, although that data is limited at the present time.

Mr. Wyden. If you considered the predicament of all the people who can't pay, could you give us an estimate of the number of people who can afford your drug?

Mr. Haigler. I have no data on that at all, Mr. Wyden.

Mr. Wyden. Then you must not have considered all those other people. You had to have made some rough calculations, otherwise you'd be pricing yourself out of the market all together.

Mr. Haigler. We didn't make any calculations as to how many patients could or couldn't afford the drug. The matter of payment for drug therapy is, we believe, not just a concern for us alone; a concern for health authorities, too.

Mr. Wyden. We certainly agree with that. But I think the process you've described is pretty close to a process of setting the price at random. I've asked you whether you considered all these people who couldn't pay, and the limitations of the government programs. I then asked specifically if you could give us an estimate of how many people would be able to afford the drug, and you said, no.

Mr. Haigler. I don't think—I know that we don't have the answer to that question, sir. And I don't know that anyone has the answer to that question, how many people will not be able to afford the drug.

Mr. Wyden. Did you assume that AIDS patients are going to come up with the money? Or did you assume that the government was going to come up with the money?

Mr. Haigler. I guess we assumed that the drug, if it was an effective drug, that the drug would be paid for in some manner by the patient himself out of his own pocket, or by third-party payers, whether insurance companies or by employers with insurance programs, or by the public health authorities if in fact the patient himself could not pay for it. We really didn't get into a lot of calculations along those lines.

Mr. Wyden. How much if the bill did you think the Government might pay? It just seems to me, you are all basically doing this in the dark. I asked you a question with regard to some of the gut issues; how many people you think will be able to afford it? What are we going to do about the people who can't? It just seems to be very murky ground, and I don't get any indication that the company has made any calculations at all.

Mr. Haigler. We certainly made calculations, as I said, about what costs we've had in it, our need to recover those costs, and tried to take into account the fact that it is an expensive drug. In terms of trying to determine exactly how many patients could afford to pay for this drug out of their own pockets, we really didn't get into that at all.

Mr. Wyden. I know overseas things are very different. Some have national systems and can tell a company, such as Burroughs

Wellcome, exactly what they are going to pay. I gather that the United States price doesn't take that into account.

Mr. HAIGLER. I can't speak to what will happen overseas, Mr. Wyden.

Mr. WYDEN. I didn't ask about overseas. We know what is happening overseas. The United States pricing structure doesn't take what is gong on overseas into account, does it?

Mr. HAIGLER. I really don't understand your question.

Mr. WYDEN. Let me say it again. Overseas with the nationalized systems, the government tells the company exactly what they are going to pay. So you have a process for making these calculations. The American pricing structure doesn't take that into account, does it?

Mr. HAIGLER. The American pricing structure is a free pricing structure, yes.

Mr. WAXMAN. Will the gentleman yield?

Mr. WYDEN. Be happy to yield to the chairman.

Mr. WAXMAN. The American pricing structure is based on monopoly that we give to a manufacturer of a drug as an inducement to make the investments for research and development to produce new drugs. But we, nevertheless, give a patent which is a monopoly, and therefore, when you decide what would be an appropriate price you're basing your decision with the knowledge that you have monopoly control over that drug.

Mr. WYDEN. I just have one other question and we'll move off this pricing issue. If AZT could prevent infection from turning into full-blown AIDS, obviously a large amount of treatment costs could be saved. Does Burroughs Wellcome have any trials underway on early intervention with AZT?

Mr. HAIGLER. That is a question I think Mr. Barry can answer.

Mr. BARRY. We obviously have some trials continuing to go on with AIDS-related complex, ARC, and we will be initiating a study in asymptomatically infected patients in the relatively near future, within a few months.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden. Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman. Who's responsible for the name AZT? Is that your company?

Mr. BARRY. That's correct. Its name right now is, its trade name is RETROVIR, and its U.S. approved name is Idovudin.

Mr. DANNEMEYER. Have you applied for a patent?

Mr. BARRY. Yes, we have.

Mr. DANNEMEYER. When?

Mr. BARRY. I can't say exactly. I think it was about a year and-a-half ago.

Mr. DANNEMEYER. And your company has the capacity to produce drugs that will treat about 30,000 people a year, right?

Mr. BARRY. At present. But as Mr. Haigler emphasized, that circumstance is rapidly evolving and may be improving above that. We just can't say right now.

Mr. DANNEMEYER. What claims do you make for this drug? Will it cure a person with AIDS to make them healthy?

Mr. BARRY. No, it will not cure a patient with AIDS, if by cure we mean elimination of all vestiges of the virus from their body forever. What it does do is it decreases their mortality rate. That is, decreases the chance they have of dying, at least over the now nine or more——

Mr. DANNEMEYER. Wait a minute. It won't cure it. They're going to die, aren't they?

Mr. BARRY. Some will. Whether all of them will die or not is difficult to say because the clinical studies have been going on—the first patient received the drug in July of 1985. The clinical studies have only been going for 18 months.

Mr. DANNEMEYER. You're not claiming it will cure AIDS.

Mr. BARRY. That's correct.

Mr. DANNEMEYER. What you're saying is it will prolong——

Mr. BARRY. It improves the quality of life of patients with AIDS and certain patients with AIDS-related complex, those who manifestations of severe immune dysfunction. And it decreases their chance of dying, at least over the observation period, which has now been extended from 6 to greater than 9 months. And we have some patients who have been on the drug for over 18 months and are doing well. Now whether they will continue to do well, or whether all patients can tolerate the drug that well and have an improvement in their quality of life for what period of time, we don't know. And we have to continue to observe these patients.

Mr. DANNEMEYER. How long have we been administering this drug to patients in this country?

Mr. BARRY. Since the beginning of July of 1985.

Mr. DANNEMEYER. How many patients have received it?

Mr. BARRY. Over 5,000 patients have received the drug, but not beginning in July. Many of those patients are patients who have been on the treatment IND which began—investigation of new drug exemption—which began in October of 1986. But we have over 200 patients who have gone well over 9 months now on the drug. And we have a smaller number who have gone over a year.

Mr. DANNEMEYER. How often is the drug taken?

Mr. BARRY. The drug is taken every 4 hours.

Mr. DANNEMEYER. Through what form? Is it orally?

Mr. BARRY. It's in capsules. Two capsules every 4 hours around the clock.

Mr. DANNEMEYER. And the cost per patient per year is $8,000 to $10,000?

Mr. BARRY. That's correct.

Mr. DANNEMEYER. I was interested when you were asked about how you projected your costs in the free enterprise that exists in this country, you definitely dodged any revelation of the internal machinations of the pricing projection, which I think frankly, you have the right to do. I think that's proprietary information and you can charge in our system just what the market will bear.

We may in our society be at a very profound public policy position given the epidemic we are facing, that from a public policy standpoint we may have to look at the way you are costing this drug which will be available to the public. Because if your patent is granted, you've got a patent on the drug that will alleviate human suffering, which the taxpayers of this country for humanitarian reasons have said publicly will be available to any person on the perceived need of the provider independent of the ability of the recipient to pay as a public policy. We all know we've said that.

So we're talking about $10,000 per patient per year. And the Surgeon General has said we'll have 270,000 people with AIDS in the next 5 years. And I think that's low. That's 54,000 a year times $10,000 would be a half a billion dollars just in drug costs to take care of these people. Not to cure them, but to hopefully make a better life for them.

And the nature of our system, the competitors out there are at liberty to develop a competitive drug which will render your drug, frankly, less desirable in the marketplace. We all know that. Hopefully, they'll come up with one that will bring a little discipline to your price. That's our system.

And maybe some scientist can develop a drug that, as I say, will treat this disease more effectively at a price that is more attractive to those in this country who obviously are going to have to pay for it, namely the taxpayer.

How long had you been working on this drug before it began its clinical trials in July of 1985?

Mr. BARRY. Approximately just under 1 year, about 9 months.

Mr. DANNEMEYER. What do you know about what your competitors are doing? Any knowledge about that. Do the trade journals talk about it?

Mr. BARRY. Well, there are certain compounds that are in Phase I or Phase II studies, and we are aware that they are in studies. We, ourselves, are continuing to look for new and better and less toxic therapies for AIDS, as are a number of other companies.

Mr. DANNEMEYER. To your knowledge, have there been any other applications for patents from producers of drugs that are designed to treat persons with AIDS?

Mr. BARRY. Oh, yes, a very substantial number.

Mr. DANNEMEYER. How many?

Mr. BARRY. I don't know the number, but a very substantial number.

Mr. DANNEMEYER. How many are currently being clinically prescribed by medical personnel for relieving symptoms of ARC or AIDS today that you have knowledge of, besides AZT?

Mr. BARRY. Well, there are none that have been shown effective in that area. There are clinical trials of at least three or four different chemical entities and probably a variety of immune therapies, four or five of those. But none are being prescribed in the usual therapeutic sense for the treatment of these diseases.

A large number of drugs are being used to treat the complications of AIDS, such as pneumocystis carinii pneumonia, CMB retinitis, a wide variety of other infections that these patients have.

Mr. DANNEMEYER. Has your company considered the possibility of licensing the production of this drug by other companies, so that the total produced will come closer to fitting the need of society than the capacity of your company to produce?

Mr. HAIGLER. If I may, Mr. Dannemeyer, I might speak to that point.

We have not considered licensing. We don't think that in the case of RETROVIR that compulsory licensing would accomplish anything.

As regards the supply situation—

Mr. DANNEMEYER. Wait just a minute, sir. I don't understand that.

I'm not familiar, of course, with the production of a drug, but other drug companies, I suspect, are, and if your capacity only permits you to produce enough to service 30,000 patients a year, and we're going to have more patients than that in the United States and probably worldwide, doesn't it appear prudent, from a public policy standpoint, to be thinking about making other productive capacities of drug companies in America able to produce this drug as well.

Mr. HAIGLER. The supply situation, as we said, is improving rapidly. We expect it to substantially resolve itself in the near future.

As far as the ability of anyone else to get to a very high level of production capacity for this particular drug before we have resolved the situation ourselves, I don't know that, but I would doubt it. I just don't think that compulsory licensing in this particular case would improve the supply situation.

Mr. DANNEMEYER. What's the problem in terms of producing more? Is it a lack of supply or a lack of capacity to assimilate——

Mr. HAIGLER. It's a matter of having had to, in the matter of just a couple years time, go from a point of practically no material at all being produced anywhere, except in grams for laboratory purposes, to where we are today, producing tons and tons of the material and having to gear up our production facilities and production capacity to be able to produce these tons of material in those quantities. Usually that takes a pretty good while.

Mr. WYDEN. Would the gentleman yield?

Mr. DANNEMEYER. I sense from what you're saying—go ahead.

Mr. WYDEN. Well, the gentleman has touched on an important area. I'm just very curious as to what will happen when the next drug comes along. What will the policy be for handling that?

Mr. HAIGLER. You mean a drug from us? Or a drug from someone else?

Mr. WYDEN. You, or someone else.

Mr. HAIGLER. Whose policy?

Mr. WYDEN. Well, I think it's really the Government's policy. This is such a vague area that you just wonder how the next one is going to be handled.

Mr. HAIGLER. Well, I can't speak to the next one. I can just say that we do believe that the supply situation is evolving very rapidly, and very shortly we're going to be—we'll have that resolved.

Mr. WYDEN. I thank the gentleman.

Mr. WAXMAN. Thank you, Mr. Dannemeyer. The gentleman's time has expired.

Mr. Sikorski.

Mr. SIKORSKI. Just a couple of questions. Earlier you said that the pricing mechanism was a reflection of a host of things—return on investment, production cost, R&D.

Then as I understand it, analysis of R&D was fuzzy. You couldn't identify the R&D cost. And then Mr. Wyden was told that you used R&D costs as the basis for price again.

How can you use them if you don't know them, if they can't be rationally segregated out?

Mr. **Barry**. Well, I wanted to emphasize that the research costs are great, but the precise costs would be considered proprietary information. But I was making the point that the cost of clinical trials, which I believe that the chairman was referring to, was not significantly less than the clinical trials for most any other drug, because of the extreme expense in studying these patients.

We accelerated clinical trials, and we had a limited number, but it didn't lower our costs significantly. It merely compressed them into a shorter timeframe.

Mr. **Sikorski**. Let me understand this. You know the R&D costs. They're defined. They're just not available to us in this kind of forum because of your proprietary concerns.

Mr. **Barry**. That's correct.

Mr. **Sikorski**. What would you say to the cynics who would say that your pricing is a reflection of an exclusive market, an analysis of the short-term nature of that market, and "get while the getting is good?"

Mr. **Barry**. I think I'd say they were wrong. The costs that we have are a reflection of all the multitude of factors that Mr. Haigler listed, not only the cost of research and development, the cost of raw material, the expense of scaling up, capital investment, and in particular the uncertainty of the future—that is, how long will this drug be considered to be the drug of choice or even preferable for any of the patients infected?

Mr. **Sikorski**. Have you focused—this drug is not without some severe, serious side effects; is that correct?

Mr. **Barry**. That is correct. A number of the patients who receive the drug, particularly those who have very poor bone marrow functions before they receive it, have a depression in that marrow function, which is manifested by a significant anemia and at times what's called a granulocytopenia—that is, a lowered number of white cells.

Mr. **Sikorski**. There are some toxic effects other than bone marrow suppression, aren't there?

Mr. **Barry**. Those are the primary toxic effects. There have been some reports of patients who have had headache and nausea and so on. Those tend to be much milder and much more difficult to differentiate from the baseline symptoms that many of these patients have.

Mr. **Sikorski**. Thank you.

Mr. **Waxman**. Thank you, Mr. Sikorski.

To put this thing in perspective, I do want to go back to where I started, and that's that you have done an outstanding job in producing this drug. It has been desperately needed. You've taken the risk. You've made the investments, and now you have a drug that means life or death for a certain period of time for many, many AIDS patients.

But in setting your price for that drug, you have the ability to set it under a framework where you recognize you have a monopoly over that drug. So you could figure to recoup your research and development investment and all your other investments, and to get a profit on top of that—you're entitled to it.

The question is: What is an adequate profit when you've got a drug that, if you set it at a price that's going to be too high, some people are going to have to, by the nature of economics, go without this lifesaving drug?

And I gather from the answer to questions from Mr. Wyden, while you had many considerations that you took note of in setting your price, one was not the ability of the patient to pay. Your expectation was that those people who wanted to buy this drug will come up with the money, and if government couldn't abide by the idea of people going without the drug because it meant death to those people who couldn't afford it, that the Government would step in.

Well, that offers a real dilemma to us. In the hospital sector, we have DRGs where we have said to the hospital, "This is what we think is reasonable for you to get paid," and we established the amount.

In other areas where we have monopoly control over a service or a product, Government has stepped in as well and established what would be a reasonable return on the investment.

We can't second-guess your evaluation of a reasonable return on your investment, since you're not telling us what your investment was. But then even if you did tell us what your investment might be, you have the other factors which you appropriately raise: What is the future marketability of this drug, other competitors, et cetera.

I don't want to be critical of you, because you're operating within the system that you didn't create, and you're benefitting from it, and you've done well for society in producing this drug. But it highlights the dilemma for us.

Mr. Dannemeyer said that the drug would be paid for. I guess with our next series of witnesses, we're going to try to determine whether that's the case, whether the drug will be paid for, because otherwise the reality will be that those who can't pay for it will go without.

Mr. WYDEN. Mr. Chairman, could I just ask one other question on the pricing matter?

Mr. WAXMAN. Sure.

Mr. WYDEN. You know, again, I think the chairman has stated my concerns very well. But let me try another approach with respect to this pricing issue.

Why didn't you set the price at $100,000 per patient?

Mr. HAIGLER. Well, I think that—you know. How can I answer that question? I think that would have been completely out of the realm of anything reasonable at all. We had to set the price at a reasonable level, and I would like to say also, in rebuttal to your statement about the needs of patients, we have taken into account, we think, the very real needs of the patients for whom this drug was developed. We've had a great concern about this.

Our people at Burroughs Wellcome Co. pride themselves on producing drugs that will help alleviating illness and provide a better life to those people who have medical problems. And I think one of the prides that we have here is being able to produce this drug that's going to help a lot of people.

So I do think the needs of these patients were very carefully considered. In terms of trying to, in our own system within our own company, decide on how many patients could or couldn't afford the drug, we had no way of determining that.

We are trying to set the price based on what we think is a reasonable price for this drug that is shown to be effective for this particular disease.

Mr. WYDEN. The chairman needs to move on.

I must tell you, I'm still unclear about how you arrived at $10,000, rather than $30,000 or $25,000. I appreciate your feeling that $100,000 is unfair. But I must tell you that I think the pricing system is close to a random system.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden.

Gentlemen, we appreciate your testimony, and I think you summarized your position well in your last statement. I appreciate it.

Mr. HAIGLER. Thank you, Mr. Waxman.

Mr. WAXMAN. For our next witnesses, we wish to call forward Dr. Robert Windom, Assistant Secretary for Health, Department of Health and Human Services, and Dr. William Roper, Administrator of the Health Care Financing Administration, Department of Health and Human Services.

Let me at this time ask unanimous consent that all members be permitted to insert an opening statement at the appropriate point in the record.

Without objection that will be the order.

Dr. Windom and Dr. Roper, we want to welcome you to our subcommittee hearing this morning. Your prepared statements will be made part of the record in full, and we'd like to ask you if you each would summarize in around 5 minutes.

STATEMENTS OF ROBERT E. WINDOM, ASSISTANT SECRETARY FOR HEALTH, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND WILLIAM L. ROPER, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. WINDOM. Thank you, Mr. Chairman and members of the committee.

Dr. Roper and one that is very much I are here to discuss AZT, azidothymidine, which is an experimental drug which has proven to be of value in the treatment of certain patients with AIDS, acquired immune deficiency syndrome.

With me today are Mr. Lowell Harvison, Deputy Assistant Secretary for Health; Dr. Maureen Myers, Chief of the Treatment Branch of the AIDS Program at the National Institute of Allergy and Infectious Diseases; Dr. Bruce Chabnor, who is Director of the Division of Cancer Treatment at the National Cancer Institute; and Dr. Gary Noble, who is the AIDS Coordinator for the Public Health Service.

With your permission, then, I would like to have my entire statement submitted for the record, and I will give you a summary.

To date, 31,982 AIDS cases have been reported in this country with some 18,462 deaths. We estimate that 1 million to 1.5 million more Americans are infected by the AIDS virus.

Remarkable progress has been made in research on AIDS. Still, as we've heard before, we have no effective cure, and general availability of an effective AIDS vaccine is some years in the future.

I would like to highlight the elements of the PHS Drug Development Program. We have developed a special process to supplement the normal, private-sector drug development system. It is a collaborative program of the NIAID and the NCI established in 1986 to identify potentially effective and therapeutic agents and move them carefully and systematically through a process which will make them available to the public both quickly and responsibly.

Two committees have been established by the Public Health Service to guide the drug selection process at the National Institutes of Health. After candidate drugs are identified, they must be produced in large quantities and distributed to investigators for preclinical and eventually for clinical testing.

Scale-up production and animal studies of toxicology, pharmacology, and bioavailability are performed on candidate drugs, under contract, for AIDS prior to initiating clinical studies in man. Once animal studies have identified a dose with potentially acceptable toxicity, then initial small clinical studies can begin in patients.

Once a drug is approved for use in patients, it may be evaluated in the NIAID-funded Aids Treatment Evaluation Units, ATEU's, for Phase I and II clinical trials of candidate therapeutic agents at medical centers throughout the Nation.

An AIDS Clinical Trial Coordinating Center was created to permit centralized data analysis for these geographically dispersed units and to ensure compliance with regulatory requirements. Data from controlled clinical trials conducted in these units are evaluated by an independent Data and Safety Monitoring Board. This oversight allows the early termination of a trial due either to efficacy or unanticipated toxicity. The attached chart outlines key events that have led up to where we are today with AZT, to your left. It also is with the presentation.

The first phase of human testing for AZT was conducted from July to December 1985 at the NCI and Duke University. Because results of these very limited trials were promising, Burroughs Wellcome began a Phase II controlled clinical trial in February of 1986. This study was designed to test the drug's safety and effectiveness in persons with AIDS who had an episode of pneumocystis carinii pneumonia, known as PCP, and in selected persons with advanced ARC.

On September 10, 1986, the Data and Safety Monitoring Board reviewed preliminary data from this study. These data showed a significant difference in survival between patients who had received AZT versus those who had received placebo. The data also showed that the group receiving AZT had a decreased number of significant AIDS-related medical complications, including opportunistic infection, compared to the placebo group.

One week later, the Board conducted a more in-depth review of the data and recommended that the placebo arm of the Phase II trial be terminated.

During this time, I convened meetings of our senior Public Health Service officials in order to independently assess developments on the latest AZT data and their implications for wider distribution of the drug. The NIH and FDA officials met with the officials of Burroughs Wellcome to develop a proposal for a coordinated approach to distribute AZT.

On September 19 of 1986 I held a joint press conference with Burroughs Wellcome to announce that all patients who were currently in the phase 2 trial would receive AZT. In addition, AZT would be made available to certain AIDS patients under a company-sponsored IND. Not only had FDA moved with great speed to grant AZT treatment IND status, the agency also waived the usual local institutional review board requirement as part of an overall effort to move without delay.

An 800 number hotline was established at NIH for AZT information and distribution. A center managed by NIAID was established for the registration of patients and their pharmacists and physicians for AZT treatment, for the receipt and evaluation of applications for use of the drug, and for the monitoring of laboratory data generated from patients receiving the drug. All this happened in less than 2 weeks.

On February 16, 1987 Burroughs Wellcome Co. assumed from NIAID full responsibility for coordinating the AZT treatment IND. From September to February, under that treatment IND 4,228 patients and 2,112 physicians were registered, 919 pharmacists were registered, and 35,200 hotline calls had been answered.

NIH scientists have continued to study AZT in AIDS patients. Clinical trials are now in progress to test the drug's safety and potential efficacy in AIDS patients with Kaposi's sarcoma, pediatric AIDS patients and AIDS patients with dementia and other related neurological disorders. It is worth stressing the AZT again is only a first step.

AZT has significant toxicity in some patients, particularly in those with anemia and depressed white blood cells. Patients with advanced disease seem to be at greatest risk for these side effects. Therefore, we are continuing our antiretroviral drug development program, and in the future we can expect a number of new therapeutic strategies to emerge.

Now I want to highlight the steps the PHS has taken to make AZT available to AIDS patients. In September of 1986 the FDA established what we call a 1AA classification system for potentially useful drugs for AIDS. Assigning them the highest priority assures expedited review.

In December of 1986 Burroughs Wellcome Co. submitted to FDA a new drug application for AZT. On January 16 of this year the application was reviewed by an FDA advisory committee. The committee recommended approval of AZT for AIDS patients with certain opportunistic infections and for certain patients with advanced ARC. The committee further recommended extensive post-approval patient monitoring and reporting by the drug's manufacturer and approved of the company's intent to develop a system for controlled distribution of the drug.

As we move ahead with final approval decisions for AZT, all of these appropriate scientific issues must be waived and analyzed expeditiously. We are all aware of the important ramifications of the approval action. It's direct effects on the health of patients, its major implications for the testing and evaluation of other drugs for the treatment of AIDS, and perhaps more indirectly the precedents that they may set for the development, evaluation and approval of other drugs for the treatment of AIDS.

This is a very devastating disease, and I pledge to you that the Public Health Service remains committed to our efforts to alleviate the suffering and death it causes.

This completes my statement, Mr. Chairman. And I'll be glad to answer questions after Dr. Roper has submitted his.

[The prepared statement of Mr. Windom follows:]

Prepared Statement of Robert E. Windom, M.D.

Mr. Chairman and members of the Subcommittee, Dr. Roper and I are here to discuss AZT (azidothymidine), an experimental drug which has proven to be of value in the treatment of certain patients with acquired immune deficiency syndrome (AIDS).

To date, 31,982 AIDS cases have been reported in this country, with some 18,462 deaths. We estimate that 1 million to 1.5 million more Americans are infected by the AIDS virus and can spread it to others, even though they may currently show no signs of illness. Present data indicate that approximately 20 to 30 percent of these persons can be expected to develop AIDS itself within the next 5 years.

Remarkable progress has been made in research on AIDS, including identification of the AIDS virus; ensuring the protection of the blood supply and clotting factors used by hemophiliacs; subsequent identification of AZT, an agent which has been shown to prolong the life of a select group of AIDS patients; initiation of clinical trials; and development of public health guidelines. Still, we have no effective cure, and general availability of an effective AIDS vaccine is some years in the future.

DRUG DEVELOPMENT

Before proceeding with a discussion of AZT, I would like to review the elements of the PHS drug development program. Because of the importance that the PHS places on AIDS, we have developed a special process to supplement the normal private sector drug developmnt system. It is a collaborative program of the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI) established in 1986 to identify potentially effective therapeutic agents and move them carefully and systematically through a process which will make them available to the public both quickly and responsibly.

Two committees have been established by the PHS to guide the drug selection process at the NIH. The NCI has the lead responsibility for the Preclinical Drug Decision Network Committee. This committee is responsible for developing effective agents against the AIDS virus; evaluating the antiretroviral activity of candidate agents from screening programs, drug development programs and other sources; and, bring candidate agents through appropriate preclinical evaluation and development.

The NIAID has the lead responsibility for the AIDS Clinical Drug Development Committee. The objectives of this committee are to review and evaluate candidate agents or therapies to control HIV infections, opportunistic infections and malignancies and to reconstitute the immune system. Candidate agents approved by this committee are recommended to the NIAID for clinical evaluation in the AIDS Treatment Evaluation Units (ATEU's).

After candidate drugs are identified, they must be produced in large quantities and distributed to investigators for preclinical and eventually for clinical testing. This has been done through augmentation of existing NCI contracts that currently produce and formulate anti-cancer drugs.

Scale-up, toxicology, pharmacology, and bioavailability studies on candidate drugs are performed under contract in animals to test drugs for AIDS prior to initiating clinical studies in man. These preclinical studies are expensive and logistically complex operations.

Once animal studies have identified a dose with potentially acceptable toxicity then initial small clinical studies can begin in patients.

AIDS TREATMENT EVALUATION UNITS

Once a drug is approved for use in patients, it may be evaluated in NIAID-funded ATEU's at medical facilities around the country. These units perform multi-centered Phase I and Phase II clinical trials of candidate therapeutic agents throughout the United States. Phase I trials are intended to carefully assess the safety of the drug and to determine any phaymacologic effects that can be monitored. The number of patients entered into these pilot trials is necessarily limited until the initial assessment of toxicity is determined. As data are accumulated, studies are gradually expanded in scope and size to obtain safety and efficacy data. Phase II consists of controlled clinical trials designed to demonstrate the effectiveness and relative safety of a drug. Normally, these are performed on closely monitored patients of a limited number—seldom will the number go beyond 100 to 200 patients.

An AIDS Clinical Trial Coordinating Center was created to permit centralized data analysis for these geographically dispersed units and assure compliance with regulatory requirements.

Data from controlled clinical trials conducted in the units, are evaluated by an independent Data and Safety Monitoring Board (DSMB). This Board composed of scientists, statisticians and ethicists, periodically review data from ongoing trials. This oversight allows the early termination of a trial due to either unanticipated efficacy or toxicity.

CHRONOLOGY OF TESTING AZT

At this time, let me take a few moments to review key events that have led us to where we are today with AZT (see attachment). In 1964, a 3'-azidothymidine was synthesized at the Detroit Institute for Cancer Research (now the Michigan Cancer Foundation) under the support of an NCI grant to discover new anti-cancer agents. The drug did not show appreciable activity as an antitumor agent and was subsequently shelved.

In 1974, it was noted that AZT was active against the Friend erythroleukemia virus (a retrovirus) in a cell culture system. This observation was not pursued, because retroviruses were not known to exist in humans. For the next decade, Burroughs Wellcome manufactured AZT for non-human applications.

In February 1985, the NIC, under the direction of Dr. Samuel Broder, tested AZT and found that it was a potent inhibitor of HTLV-III *in vitro*. Burroughs Wellcome then entered into a commitment with the NCI to pursue the clinical development of AZT, and the company assumed the responsibility of doing the necessary animal toxicology. The NCI assisted by providing starting stocks of raw materials (thymidine) for manufacturing the drug.

The *in vitro* data demonstrated the activity of AZT against multiple strains of human HTLV-III, and defined a range of *in vitro* dosing.

In June, 1985, an Investigational New Drug Application (IND) was issued to the NCI to begin Phase I testing in patients, and on July 3, 1985, the first AIDS patient received AZT in the NIH Clinical Center. Additional patients were enrolled at both Duke University and the Nci shortly thereafter.

The Food and Drug Administration (FDA) also has provided assistance to the drug's developers through the Agency's Orphan Product Development Program. This promotes promising new drugs and biologics for relatively rare diseases including AIDS, by providing their manufacturers with the opportunity to receive tax incentives, grants, and exclusive seven-year marketing protection. AZT was awarded Orphan Drug status by FDA in July 1985.

RESULTS IN CLINICAL TRIALS OF AZT

The first phase of human testing for AZT, involving only 33 patients with AIDS and AIDS-related Complex (ARC), was conducted from July to December 1985 at the NCI and Duke University. The studies showed that the drug was well absorbed after oral administration. It was also determined that AZT does cross the blood brain barrier. This is important because involvement of the central nervous system is common in patients with HIV infection. The patients enrolled in the Phase I studies continue to be followed for evidence of toxicity, and for evidence of the effect of the agent on the eventual outcome of the disease. The longest period of patient observation has now reached 18 months.

Because results of these very limited trials were promising, Burroughs Wellcome began a Phase II controlled clinical trial in February 1986. This study was designed to test the drug's safety and effectiveness in persons with AIDS who had an episode of *Pneumocystis carinii* pneumonia (PCP) and in selected persons with advanced ARC. Close to 300 patients were involved in the company sponsored multicenter trial, which was a randomized comparison of AZT and placebo. Prior to starting this study, the company asked the NIH to establish a DSMB to perform periodic analysis of safety and efficacy.

On September 10, 1986, the DSMB reviewed preliminary data from the study. These data showed a significant difference in survival between patients who had received AZT versus those who had received placebo. The data slso showed that the group receiving AZT had a decreased number of significant AIDS-related medical complications, including opportunistic infections, compared to the placebo group. This was true of both patients with AIDS and certain advanced ARC patients. In addition, weight gain and improvements in daily activities, as well as improvements in immune function noted during the Phase I studies were confirmed. One week later, the DSMB conducted a more in-depth review of the data and recommended that the placebo arm of the Phase II trial be terminated.

During this time, I convened meetings of senior PHS officials in order to independently assess developments on the latest AZT data and its implications for wider distribution of the drug. NIH and FDA officials met with officials from Burroughs Wellcome to develop a proposal for a coordinated approach to distribute AZT under a Treatment IND.

On September 18, led by Dr. Anthony Fauci, Director of NIAID, with the assistance of Dr. Daniel Hoth of the NCI, and officials from PHS and Burroughs Wellcome met to discuss issues of availability, distribution, and cost of AZT. In a very short time, we had devised an efficient and equitable system for the distribution of AZT.

On September 19, I held a joint press conference with Burroughs Wellcome to announce that all patients in the Phase II trial would receive AZT. Further AZT would be made available to certain AIDS patients under a company sponsored, Treatment IND.

Not only had FDA moved with great speed to grant AZT Treatment IND status, the Agency also waived the usual local Institutional Review Board (IRB) requirement as part of an overall effort to move without delay and because an adequate alternative mechanism existed for protecting those receiving AZT under this Treatment IND. The Burroughs Wellcome Company and NIH immediately collaborated in setting up an AZT Treatment IND Coordinating Center which was responsible for the distribution mechanism for making AZT available to eligible persons under the treatment IND. An 800-number "hotline" was established by NIH for AZT information and distribution. A government contract was used to establish a center managed by NIAID for the registration of patients and their pharmacists and physicians for AZT treatment, for the receipt and evaluation of applications for use of the drug, and for the monitoring of laboratory data generated from patients receiving AZT. All this happened in less than two weeks.

On February 16, 1987, the Burroughs Wellcome Company assumed from NIAID full responsibility for coordinating the AZT Treatment IND. From September to February under the Treatment IND: 4,228 patients and 2,112 physicians were registered; 919 pharmacists were registered; and, 35,200 hotline phone calls were answered.

RESEARCH

NIH scientists have continued to study AZT in AIDS patients. Clinical trials are now in progress to test the drug's safety and potential efficacy in:

—AIDS patients with Kaposi's sarcoma;
—pediatric AIDS patients; and,
—AIDS patients with dementia and other related neurological disorders.

A great deal of effort is directed at finding new dose regimens or new combinations of anti-retroviral drugs (as well as combinations of retroviral drugs plus immunomodulators). The purpose of this effort is to develop regimens that reduce the toxicity of the drug without impairing its ability to benefit patients.

It is worth stressing that AZT is only a first step. AZT has significant toxicity in some patients, particularly in those with anemia and depressed white blood cells. Patients with advanced disease seem to be at greatest risk for these side effects.

We are continuing our anti-retroviral drug development program, and in the future, we can expect a number of new therapeutic strategies to emerge.

STEPS TOWARD MARKETING APPROVAL

Finally, let me bring you up-to-date on the steps PHS has taken to make AZT available to AIDS patients. In September 1986, the FDA established a 1 AA classification system for potentially useful drugs for AIDS. This 1 AA classification assures the drug of an expedited review by assigning it the highest priority in FDA's drug reviewing divisions. In December 1986, the Burroughs Wellcome company submitted to FDA a New Drug Application (NDA) for AZT, and on January 16 of this year, the application was reviewed by an FDA Advisory Committee. Based on the data from the controlled clinical trial which showed that 19 of 137 patients on placebo had died compared to only one of 145 patients on AZT, the Committee recommended approval of AZT for AIDS patients with certain opportunistic infections and for certain patients with advanced ARC.

The Committee further recommended extensive postapproval patient monitoring and reporting by the drug's manufacturer in order to resolve important questions about the efficacy of prolonged use and possible adverse effects associated with AZT's long-term use. The Committee also approved of the company's intent to develop a system for controlled distribution of the drug.

The FDA is reviewing and analyzing the data collected on patients who were enrolled in the open-label continuation of the study in addition to the data from the placebo-controlled trial. They must decide on the basis of all this information which patients have been demonstrated to benefit from AZT despite its toxicity, and in which groups of patients further studies are needed to determine the risk-benefit ratio.

While AZT appears, in the short-term, to be beneficial, the studies have shown that it, like many active antiviral drugs, has significant side effects. it causes anemia severe enough to require transfusions and depresses the white blood cell count in many individuals. This is a reminder that it is necessary to assess the risks of such a drug very carefully, as well as its potential benefits.

As we move ahead with final approval decisions for AZT, all of these appropriate scientific issues must be weighed and analyzed expeditiously. We are all aware of the important ramifications of the approval action: its direct effects on the health of patients, its major implications for the testing and evaluation of other drugs for the treatment of AIDS, and perhaps more indirectly the precedents that may be set for the development, evaluation, and approval of other drugs for the treatment of AIDS. This is a devastating disease and I pledge to you that the Public Health Service remains committed in our efforts to alleviate the suffering and death it causes.

The issues involved in development of AZT—under conditions of tremendous public pressure—have been extremely complex and have presented enormous challenges to regulators and scientists, both outside and within government. During this time, our utmost concern has been the relief of AIDS patients but we have had to balance compassion for those who suffer from this dread disease with the very important public health issues of drug safety and effectiveness.

This completes my statement, Mr. Chairman. I will be glad to answer questions that you or your subcommittee members may have after Dr. Roper completes his statement.

AZT MILESTONES

1964—First developed in NCI extramural program and evaluated as a potential anti-cancer drug—found not effective.

1974—First shown to have activity against a mouse leukemia virus.

Late 1984—Burroughs Wellcome and NCI begin collaborative laboratory evaluation against HTLV-III/LAV.

Feburary 1985—Above collaboration identifies that the drug inhibits HTLV-III *in vitro*.

Mid-1985—First small safety trials begin in humans at NIH Clinical Center.

Early 1986—NCI publishes data on first 19 AIDS patients; begin broader placebo-controlled trial of safety and efficacy.

September 18, 1986—Data and Safety Monitoring Board recommends termination of study based on safety and efficacy data.

September 30, 1986—FDA approves Treatment Investigational New Drug application.

January 16, 1987—Advisory committee to FDA recommends approval as a prescription drug for certain subsets of AIDS patients.

Mr. WAXMAN. Thank you very much, Dr. Windom. Dr. Roper.

STATEMENT OF WILLIAM L. ROPER

Mr. ROPER. Good morning, Mr. Chairman, members of the committee. I'm pleased to be here today to talk about Medicare and Medicaid as they relate to AZT. We estimate that about 40 percent of current AIDS patients are being served by the Medicaid program, and about 1 percent of AIDS patients by Medicare. The Federal and State governments through the Medicaid program will spend more than $400 million on AIDS patients this year. Primarily because of the disability waiting period, spending under the Medicare program is currently estimated to be under $50 million a year.

Most AIDS patients who qualify for Medicaid do so by meeting the disability requirement under the supplemental security income, or SSI program. Social Security Administration has made it possible for persons with AIDS to qualify for SSI almost immediately under the presumptive disability provisions.

Also AIDS patients frequently can become eligible for Medicaid benefits as medically needy individuals through the spenddown process. Thirty-five States provide this option.

Medicare is available to disabled persons under 65 who have received Social Security disability benefits for 24 months. Since cash benefits for disability income eligibles do not begin until almost 6 months after the onset of the disability, a disabled person with AIDS would not be eligible for Medicare for almost 30 months. This waiting period certainly limits the coverage of AIDS patients under Medicare.

Under Medicaid the full range of regularly provided Medicaid services in a State are available to the AIDS patient. States have substantial flexibility to choose to cover a number of additional benefits which could assist the typical AIDS patient, such as hospice care and personal care. In addition, States may also implement innovative health care delivery alternatives through the home and community based waiver services program.

As you know, a provision of OBRA-86 set up a special waiver program for AIDS waivers, and we have approved earlier this year such a waiver for the State of New Jersey.

Prescription drugs are an optional benefit under State Medicaid programs. Every State but two has elected to offer drugs to the categorically needy. Thirty-five States provide a drug benefit for the medically needy category as well. HCFA will reimburse the States for any drugs, including experimental drugs which are provided according to Federal guidelines, except those that have been determined by the FDA to be less than effective.

Under the Medicare program, the only circumstances under which we will pay for drugs are when they are provided on an inpatient basis or incident to a physician's services. In other words, Medicare does not pay for out-patient, self-administered drugs including AZT.

In order to provide advance notice of the availability of AZT to our State Medicaid agencies we issued a program memorandum to alert the States that FDA approval of the drug AZT is likely in the near future. This information allows the States to begin immediately to revise their State formularies to include AZT if they choose to do so. We have promised to inform the States of any significant change in the status of AZT.

You've heard testimony that the estimate by Burroughs Wellcome is that the cost of AZT will be $8,000 to $10,000 per year per patient. Determining the cost of AZT to the Medicaid program is extremely difficult and involves a number of assumption that could change. For one thing, we don't know at this time whether the drug will be prescribed for all AIDS patients, or even all AIDS and ARC patients. We don't know if AZT can be produced in significant quantities to meet anticipated demand.

Given the limited information available, HCFA believes that the costs to the Medicaid program of AZT itself, not counting the cost of treating side effects as well as potential savings from reducing the number and severity of acute spells of illness could range up to $50 million this year if the drug is approved by April 1. Costs for 1988 under similar assumptions could reach $150 million. These costs would be shared approximately equally by the States and the Federal Government.

As the agency responsible for financing the Medicare and Medicaid programs, we've worked closely with Assistant Secretary Windom, the Surgeon General, the Public Health Service to make sure we are maximally coordinating our efforts in responding to the AIDS crisis. HCFA is committed as an agency to ensuring that appropriate care and services are delivered to AIDS patients. In partnership with the States, the Department and HCFA will continue to address and respond to the treatment of patients with this very serious disease.

I'd be pleased to respond to your questions.

[The prepared statement of Mr. Roper follows:]

Prepared Statement of William L. Roper, M.D.

Mr. Chairman, I am Dr. William L. Roper, Administrator of the Health Care Financing Administration. I am pleased to be here today to discuss Medicaid and Medicare payment for he AIDS-treatment drug AZT. Mr. Chairman, as you know, AIDS is one of the priority items on the Secretary's agenda. I want to assure you that Doctor Bowen and I have discussed at length the seriousness of this tragic disease and the hope of soon finding an appropriate treatment and cure.

BACKGROUND

I would like first of all to provide a brief overview of how AIDS patients qualify under the Medicaid and Medicare programs. Based on information gathered from hospitals treating Medicaid patients and data on AIDS-related disability awares, we estimate that about 40 percent of AIDS patients are served by the Medicaid program and about 1 percent are receiving care under the Medicare program. it has been estimated that the Federal and State governments, through the Medicaid program, will spend from $400 to $800 million on AIDS patients this year. Primarily because of the disability waiting period, spending under the Medicare program is currently estimated to be under $50 million annually. It should be noted that these estimates do not include the impact of the drug AZT, about which I will say more later.

MEDICAID

Most AIDS patients qualify for Medicaid by meeting the disability requirement under the Supplemental Security Income (SSI) program. In the early stages of AIDS, most patients have resources, incomes, or health insurance coverage. As the disease progresses, most patients become unable to work and, as a result, lose income and resources. At this point, they often turn to SSI to seek qualification based on disability which, in most cases, would make them eligible for Medicaid. Those who might not qualify are in the 14 States which, when the SSI program was enacted, were allowed to use the more restrictive qualifying criteria from their previous Aged, Blind, ad Disabled programs. Congress provided this option based upon the fear that States would face an overwhelming Medicaid caseload because of their eligibility under SSI.

In February 1985, SSA made it easier for persons with AIDS to qualify for SSI under the presumptive disability provision. This allows the applicant to qualify for benefits almost immediately by reducing the waiting time between applying for and receiving benefits.

Even if persons with AIDS do not qualify initially for cash assistance benefits under SSI, they frequently can become eligible for Medicaid benefits as medically needy individuals through the "Spenddown" process. People with incomes and resources above the Medicaid limits who have incurred substantial medical expenses can have those expenses subtracted from their income level, thus bringing them below the Medicaid limits. Currently, 32 States have a medically needy program covering the aged, blind, and disabled; an additional five States have this program for pregnant women and children.

In addition to SSI and medically needy coverage, another avenue of assistance for the AIDS patients is qualification for Medicaid coverage through eligibility for the Aid to Families with Dependent Children program. The individual may be a child with AIDS whose mother had contracted the disease through drug abuse, as well as the mother herself if she qualifies for AFDC. In states which have an AFDC-Unemployed Parent program, the AIDS patient could be, for example, the unemployed parent provided that that household met the program's qualifying criteria.

MEDICARE

Medicare is available to disabled persons under 65 who have received Social Security disability benefits under Title II of the Social Security Act for 24 consecutive months. The disability criteria under Titles II and XVI are the same. However, unlike SSI, cash benefits for all Title II eligibles do not begin until six months after the onset of the disability. After the "24-month waiting period" (Actually in most cases almost 30 months), a disabled person with AIDS would be eligible for both part A (Hospital Insurance) and part B (Supplemental Medical Insurance) of Medicare. Because of the relatively rapid and fatal course of AIDS, only a very small percentage of individuals with AIDS can receive benefits under the Medicare program.

SERVICES AVAILABLE UNDER MEDICAID

The scope of covered benefits under Medicaid varies considerably from State to State. All States, however, must cover certain mandatory services for almost all SSI and AFDC recipients. AIDS patients who are Medicaid-eligible receive services through hospitals, outpatient departments, physicians' offices, rural health clinics, laboratory and radiology settings, and skilled nursing facilities and home health agencies for those who are 21 years of age and older.

States may choose to cover certain additional benefits which could assist the typical AIDS patient. Some examples include clinic services, prescribed drugs, intermediate care facilities services, miscellaneous diagnostic services, and skilled nursing facility care and home health care services for individuals under 21 years of age. Other ancillary services such as personal care, private duty nursing, and rehabilitation services are also optional benefits.

States are also permitted to cover hospice services under their Medicaid programs. The Medicaid hospice benefit stresses home care, which provides an alternative to institutional settings and allows AIDS patients another choice for receipt of their care. New York has already designated one hospital as an AIDS center and expects to approve eight more. These hospitals will be required to provide a continuum of care, including hospice, nursing home, and inpatient care. New York has submitted a State Plan Amendment to HCFA to cover the hospice benefit under its Medicaid program. We are now in the process of evaluating the additional information that New York has supplied.

States also have the ability to implement innovative health care delivery alternatives through the home- and community-based waiver services program. This program gives State Medicaid programs the opportunity to pay for a wide range of care delivered at home and in the community for those who might otherwise be institutionalized. The Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) allows States to target their home- and community-based services waiver to AIDS and ARC (AIDS-related complex) patients.

On January 8th of this year, we approved the first AIDS-targeted waiver to the State of New Jersey Medicaid agency so that it might provide home treatment for patients with AIDS and ARC. New Jersey can now provide services under this home- and community-based waiver program such as personal care, medical day care, narcotic and drug abuse treatment, private duty nursing care, and intensive foster care for pediatric patients. The three-year waiver was effective March 1 and can be renewed. New Jersey has the fifth largest populaion of persons with AIDS and expects to treat 578 Medicaid-eligible AIDS patients in the first year of the waiver, at a cost of about $11 million or $18,996 per patient. The State projects that it will serve 990 patients at a cost of $20 million or $20,554 per individual in the second year, and, in the third year, 1650 patients at a cost of $36.6 million or $22,238 per individual. Based upon New Jersey's projections, the average rate of growth for total costs would be 82.4 percent.

New Mexico has also requested a home- and community-based services waiver for AIDS patients. In order to assist the State in bringing its request into conformance with statutory and regulatory requirements, we formally requested additional information regarding the proposal. Our Dallas Regional Office worked closely with the State in an effort to develop the information necssary for the waiver to be approved. We have just received the additional information, which we are in the process of evaluating.

Clearly, States have the flexibility to provide a wide range of additional services. The States with the highest number of AIDS cases, California and New York, which have recorded approximately 53 percent of all reported AIDS cases in the United States, provide numerous additional optional servicse, respectively, to their Medicaid populations.

PRESCRIPTION DRUGS

Prescription drugs are also an optional benefit under State Medicaid programs. Every State, except for Alaska and Wyoming, has elected to offer drugs to the categorically needy. Thirty-five State programs provide a drug benefit for the medically needy category as well. States may limit the number of drugs covered and the amount and scope of the benefit, for example, by restricting drug coverage to so many drug prescriptions per month. Eighteen States require copayments on prescriptions. A State determines, with the advice of medical consultants, which experimental drugs, if any, it chooses to cover under its Medicaid program. HCFA will match States' payments for any drugs, including experimental drugs, which are provided according to Federal guidelines, except those that have been determined by the Food and Drug Administration (FDA) to be less-than-effective.

The Medicare program will pay for drugs when provided on an inpatient basis or incident to a physician's service. Drugs generally are not covered under Medicare when provided on an outpatient self-administered basis. In addition, Medicare does not cover experimental drugs, which are those not approved by the FDA for marketing.

AZT (AZIDOTHYMIDINE/RETROVIR)

The drug AZT has demonstrated some success in prolonging survival among certain AIDS patients. Burroughs Wellcome, the manufacturer of AZT, now provides the drug free to the more than 4,000 patients participating in the Investigational New Drug clincial trials. The drug is now awaiting final approval by the Food and Drug Administration in order that it may be marketed as a prescription drug by the Burroughs Wellcome Company.

In order to provide advance notice of the availability of AZT to our State Medicaid agencies, we issues a program memorandum to alert them that FDA approval of the drug AZT is likely in the near future. This information allows States to begin immediately to revise their State formularies to include AZT if they choose to do so. We have promised to inform the States of any significant change in the status of AZT.

The Burroughs Wellcome Company has indicated that the drug will be $188 per one humdred 100 mg. tablets. This would mean that the resulting cost to the patient would be, depending on the individual patient's regimen and actual dosage, between $7,000 and $10,000 annually.

Determining the cost of AZT to the Medicaid program is extremely difficult and involves a number of assumptions that could change. For one thing, we do not know at this time of the drug will be prescribed for all AIDS patients, or limited to the population on which it has been tested in the Phase II Study, i.e., those with at least one occurrence of Pneumocystis Carinii Pneumonia or some other groups of patients. At this point, we do not know if AZT can be produced in sufficient quantities to meet anticipated demand. Among other unknowns is the cost of treatment for the side effects of AZT and the cost implications of its potential for reducing the incidence of acute spells of illness.

Given the limited information available, HCFA believes that the costs to the Medicaid program of AZT itself—ignoring the cost of treating side effects as well as potential savings from reducing the number and severity of acute spells of illness—could range up to $50 million in 1987 if the drug is approved by April 1 and demands for it can be met. Costs for 1988 under similar assumptions could reach $150 million.

These costs would be shared approximately equally by the States and the Federal Government.

SUMMARY

As the agency responsible for financing the Medicare and Medicaid programs, we have worked closely with the Assistant Secretary for Health, the Surgeon General, and the Public Health Service to ensure maximum coordination of our efforts in responding to the AIDS crisis. In addition, we have a HCFA AIDS coordinator, and a HCFA representative serves on the Assistant Secretary for Health's PHS Executive Task Force on AIDS.

HCFA is committed as an agency to ensuring that appropriate care and services are delivered to AIDS patients. In partnership with the States, the Department and HCFA will continue to address and respond to the treatment of patients with this serious disease.

I will be glad to answer any questions you may have.

Mr. WAXMAN. Thank you very much, Dr. Roper. Dr. Windom, there are approximately 4,500 people who are now receiving AZT for free. These are the people that are part of the clinical test. Now when AZT becomes licensed by FDA the drug is not going to be made available free. They're going to charge $8,000 to $10,000. Who will pay for these people? We've already had them on the drug. If they don't continue with the drug, they'll die. Who will pay for them?

Mr. WINDOM. Mr. Chairman, there are a number of those patients who are continuing on those trials. Also because there's postmarketing surveillance necessary to follow up, so a number of those will be receiving the drug, as they are now, at no expense to them.

Mr. WAXMAN. Who will pay for it?

Mr. WINDOM. The drug company is providing that under certain circumstances for those who are continuing in certain trials that will be ongoing. Otherwise for the open market, that will be based upon the individual, third party or Medicaid or whatever. There will be a number of sources.

Mr. WAXMAN. How many of the 4,500 would then be in the category for which the company would continue to pay?

Mr. WINDOM. I don't have that figure, Mr. Chairman. I don't know the exact number.

Mr. WAXMAN. Do you know the range? Are we talking about three out of the 4,000? Are we talking about 50 out of the 4500? We'd like that figure and we'll get it for the record.

Mr. WINDOM. We'll provide that for the record, sir.

Mr. WAXMAN. But the other point is, whatever number of those people in that group that have gone through this clinical trial, don't we have a responsibility for them since they've been part of this trial to establish the efficacy of this drug, not to just suddenly push them aside on their own? If they can't afford it, they're just going to be out of luck?

Mr. WINDOM. I'm not aware that anybody is going to be taken off the drug because they cannot pay. That would have to be evaluated on individual circumstance.

Mr. WAXMAN. You would say it would be unethical not to have that drug available to all those 4,500 people that have already been part of the trial and that already are getting the drug. So if they don't get it there are serious consequences.

Mr. WINDOM. Yes, sir.

Mr. WAXMAN. Now as you've outlined the NIH has contributed a great deal toward the development of AZT. The Public Health Service has set up the AZT program, and the FDA has acted in near record time to get this drug out to market. So we've had a lot of government assistance in moving this drug along.

Do you believe that the Burroughs Wellcome price of $8,000 to $10,000 per person per year is a fair price?

Mr. WINDOM. Mr. Chairman, I can only comment that I do not know the exact way by which they have come about their pricing mechanism and would have to defer to their best judgment, and feel that they're doing this to meet their requirements. Again, I don't know the intricacies of that.

Mr. WAXMAN. Do you intend to get the records from them to look at their investment cost, to second guess their evaluation as to whether this is a reasonable price?

Mr. WINDOM. I do not intend to. I don't think that is in the purview of our position, our work.

Mr. WAXMAN. How many other drugs besides AZT are in clinical trials now?

Mr. WINDOM. There are approximately 10 or 11 other trials that are going on with other drugs.

Mr. WAXMAN. We'd like a list of those for the record, if you could provide that to us. We'd like to know how many are in clinical trials, how many drugs have been proposed for trials to the NIH drug selection committee, and get the complete update on that.

We've heard Dr. Roper talk about the financial costs of AIDS care. Are there any clinical trials underway for early intervention drugs that may stop the virus before it becomes a full AIDS case?

Mr. WINDOM. No, this is the first drug that actually we have available to be used. So we have no drug available at this point as far as showing to effect upon the early stages of AIDS.

Mr. WAXMAN. Does NIH plan to initiate such research?

Mr. WINDOM. There are a number of these drug trials that are presently in effect, new drugs that may be appropriate for the early stages. We'll have to wait to see what their trial results are.

Mr. WAXMAN. Now let's talk about who's going to pay for the drug. If a patient can afford it, the patient will pay. If the patient has insurance that will pay for it, the insurance company will pay. Dr. Roper, you indicated that Medicare, while it covers the disabled generally does not cover AIDS patients because there's a 2-year waiting period and they generally die before that 2 years eligibility is met.

So Medicaid becomes the government health care insurance system that will pay for care for these patients. That's after they become eligible on a spenddown basis——

Mr. ROPER. After they become eligible for SSI or spenddown under medically needy programs, yes.

Mr. WAXMAN. So they become impoverished and then when they're eligible on that basis Medicaid will come in.

Mr. ROPER. Yes.

Mr. WAXMAN. Now in the Medicaid program many States set a dollar limit on prescription drugs?

Mr. ROPER. Yes, they're able to do that.

Mr. WAXMAN. Florida has one of the highest incidences of AIDS in the country. Florida limits Medicaid reimbursement for drugs to $22 per month. AZT will probably cost between $600 and $800 a month more than that. What will a person with AIDS do under the Florida Medicaid program?

Mr. ROPER. They would not be eligible unless the State of Florida changed that limit. I would expect a number of States to make those kind of changes. AZT is a unique drug. AIDS is a unique illness.

Mr. WAXMAN. Why would you think the States would want to change their limits? I mean, after all, if the drug company works on the assumption that in pricing the drug somebody is going to pay for it, why wouldn't the States work on the assumption that if they put the limits on it that the Federal Government will be stuck with it because somebody else, i.e., the Federal Government, will pay for it? Why would the States want to incur this additional cost?

Mr. ROPER. Because they have a responsibility to their citizens.

Mr. WAXMAN. And what will be the Federal Government's response?

Mr. ROPER. We operate the Medicaid program in concert with the States.

Mr. WAXMAN. Right now under the terms of the Medicaid program may a State refuse to reimburse for a specific drug, even if it's life-sustaining?

Mr. ROPER. Yes. States are free to determine the formulary or the list of drugs that are covered under their Medicaid program. Some States have an open formulary, meaning they cover any drug that's FDA approved. Others have more limited lists. That came about because of a desire to save money, to conserve costs in the program.

Mr. WAXMAN. What would an AIDS patient do in a State that doesn't pay for prescription drugs or one that refuses to pay for AZT?

Mr. ROPER. They would not be eligible for AZT payment under the Medicaid program in their State.

Mr. WAXMAN. They would go without.

Mr. ROPER. Or find some other means of payment.

Mr. WAXMAN. Now under the Medicaid program, 19 States including New York and California have a State formulary or list of drugs that will be paid for. You say that you've notified States of the possible approval of AZT. How many States have moved to add AZT to their reimbursement list?

Mr. ROPER. Twenty-six States have open formularies. And what that means is immediately on FDA approval the drug will be covered under those States. Another 10 States have told us that they will cover AZT almost immediately. The others we have not yet heard back from.

Mr. WAXMAN. We'd like to get a list from you of the States.

Mr. ROPER. Surely.

Mr. Waxman. How long does it take to add a drug to the State formulary?

Mr. Roper. Again, it varies widely. Some States do so immediately. Others have a process of committee meeting to review the drug and make a determination for the State Medicaid program.

Mr. Waxman. Some States amend their formulary once or twice a year, don't they?

Mr. Roper. That's correct.

Mr. Waxman. Some may refuse to pay at all.

Mr. Roper. That's correct.

Mr. Waxman. Some may move to add AZT on an expedited basis.

Mr. Roper. Yes.

Mr. Waxman. So it's now up to the States.

Mr. Roper. Yes.

Mr. Waxman. What will an AIDS patient do if a State does not add AZT to its formulary?

Mr. Roper. He will not be eligible for it under the Medicaid program.

Mr. Waxman. Certainly we're talking about a catastrophic health problem. What help would the administration's proposal for catastrophic health insurance be in paying for the $10,000 a year for AZT?

Mr. Roper. The provision to provide better financing in the Medicare program would not affect AZT and AIDS patients. Another part of the Secretary's proposal that the President has recommended to the Congress is, assistance to the States to State actions like this one under the Medicaid program to provide better coverage.

Mr. Waxman. We have a proposal before us from the administration called catastrophic health insurance and it covers—

Mr. Roper. That's specifically the Medicare part.

Mr. Waxman. So it wouldn't cover AZT?

Mr. Roper. No.

Mr. Waxman. Even though it would a medical catastrophe. Neither the Medicare program nor the Administration's plan has an out-patient prescription drug coverage. The administration's plan affects only Medicare beneficiaries and very few AIDS patients live long enough to qualify for Medicare. So what's being called catastrophic health insurance before the Congress will not take care of this particular kind of medical catastrophe.

In earlier testimony before this subcommittee HCFA said that it anticipates that 23 percent of AIDS costs will be born by Medicaid. Today you say that 40 percent of AIDS patients will be served by Medicaid. Could you explain the difference?

Mr. Roper. The figure is 40 percent in outpatients and 23 percent in the costs, because of the spend down process of becoming Medicaid eligible.

Mr. Waxman. Mr. Haigler suggested that AZT actually lowered treatment costs for AIDS patients since it may prevent frequent recurrences of disease, and then lower hospitalization rates. Do you agree?

Mr. Roper. That is a logical presumption, but I don't know the evidence. I haven't reviewed the figures.

Mr. Waxman. Well, it's going to—healthier people are not going to need to be in the hospital. Wouldn't that give you the conclusion that it would save money, that you'd otherwise have had to pay the hospitalization?

Mr. ROPER. Indeed, yes.

Mr. WAXMAN. If it can be shown that the drug will lower costs, would you support a mandatory Medicaid benefit requiring all States to supply AZT?

Mr. ROPER. No, because the Medicaid program is operated in concert with States, Federal and State partnership, and the States for a variety of reasons, ought to be given substantial latitude to operate the program. We trust the judgments of the states.

Mr. WAXMAN. Under Federal law, we require that the Medicaid program provide health care services for certain population groups that are in the bottom economically, and we require that they provide certain services. We leave some things as optional and leave it to State discretion, but some things we mandate.

If we saw that States decided they didn't want to cover AZT for these patients, and I think we all agree ethically that we must provide this, we must as a society make sure these people don't go without the drug, and die because of the fact they can't afford it. Isn't there a Federal responsibility? We talked about the State responsibility to take care of their citizens. Isn't there a Federal responsibility to take care of our citizens?

Mr. ROPER. And the Federal Government is discharging that responsibility in the Medicaid program.

Mr. WAXMAN. By shifting the burden to the States?

Mr. ROPER. Not at all. Because by operating the program in concert with the States, it's a Federal-State partnership.

Mr. WAXMAN. Yes, but we are letting the States decide rather than decide at the Federal level.

Mr. ROPER. That's been the nature for 21 years.

Mr. WAXMAN. That's not the nature of every service. That's the nature of some services, and we're talking about one that is unlike others we've had, not completely unlike, but unlike others we've had because of the high cost, and clear inability for people who are on Medicaid to be able to come up with $10,000 a year.

There's no reference to it in your statement, but I don't need to remind you that the fiscal year 1988 budget that the administration submitted to Congress calls for a cap on the Federal Medicaid spending, which would then ask the States to pick up at least $1.3 billion next year, according to the Congressional Budget Office. If AIDS related Medicaid spending will be $400-800 million this year as you've testified, how do you expect the States to cope with the even greater financial consequences of the epidemic next year under that proposed cap?

Mr. ROPER. The other part of the cap is a proposed enhancement, substantial enhancement, of the States' ability to manage their Medicaid programs more efficiently and given the ability to do that, we think they could pay for more services, deliver more services, even with a cap.

Mr. WAXMAN. Well, we've had reductions in Federal dollars to the States in the past, and the way they've handled it is by reducing services and reducing eligibility. One would expect if that's how they meet the fewer Federal dollars, under the Medicaid program in the past, they're not going to be talking about expanding Medicaid formularies to pay for AZT, which is going to be so very, very expensive.

Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

Mr. Windom, you're a licensed physician in the State of Florida, right?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. How long did you practice there?

Mr. WINDOM. 26 years.

Mr. DANNEMEYER. And did you have a general practice?

Mr. WINDOM. General internal medicine, yes, sir.

Mr. DANNEMEYER. Are you familiar with the law of the State of Florida that calls for the reportability of certain communicable diseases?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. How many diseases made are reportable by the law of the State of Florida, that a physician encounters, roughly?

Mr. WINDOM. I don't have that list in front of me, but it is quite large, probably 15 or more. I just don't know exactly.

Mr. DANNEMEYER. And among those that are reportable, some are curable and some are non-curable, right?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. Give me an example of some that are curable that are reportable. For example, syphilis and gonorrhea. Are they reportable in the State of Florida?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. Those are curable communicable venereal diseases, aren't they?

Mr. WINDOM. Yes, but we see some cases now that are resistant, but potentially they are curable.

Mr. DANNEMEYER. Do you support the policy, the public health policy, of making curable communicable venereal diseases reportable?

Mr. WINDOM. That is a provision within the State health program, which they do, and are allowed to do, and they make their decisions, and I go along with that.

Mr. DANNEMEYER. You support them?

Mr. WINDOM. The State decision is to make that.

Mr. DANNEMEYER. That's been standard public health response to deal with communicable disease throughout this country for at least during the years you've practiced medicine. Isn't that right?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. You believe that to be sound public health policy?

Mr. WINDOM. That determination is sound, yes, sir.

Mr. DANNEMEYER. Then let's take a person with a virus for AIDS. Mr. Koop—Dr. Koop, the Surgeon General of the United States, in his report to the Nation last October, in that report said, we must presume that every person with the virus is capable of transmitting that virus to another human on a transfer of bodily fluids. Isn't that right?

Mr. WINDOM. Yes, sir.

Mr. Dannemeyer. Therefore any person with the virus has by definition, a communicable disease, right?

Mr. Windom. Potentially communicable.

Mr. Dannemeyer. Do we have a cure for the virus today?

Mr. Windom. No, sir.

Mr. Dannemeyer. So we have in the words of Dr. Koop, I think at one point in his report, it's estimated we have 1-2 million Americans with the virus in their blood, right?

Mr. Windom. Yes, sir.

Mr. Dannemeyer. The current estimate is those that have the virus that will go on to get the disease is about 50 percent, right?

Mr. Windom. 25-50 percent is the figure used.

Mr. Dannemeyer. All right. One of the things that prompts me on this line of question is the rule of paradox in the public health response to deal with this epidemic in America.

You say as a public health official and a private practicing physician, that you support the concept of reportability for curable communicable venereal diseases, such as syphilis and gonorrhea. Will you please tell this panel and the people of this country, how the public health authorities of this Nation can justify the public position you now pursue, of attempting to defend that we will not call to be reported those with a non-curable communicable venereal disease? I'll say it again. How in the world do we justify a system which mandates the reportability of a curable communicable venereal disease, and attempt to defend making not reportable, a non-curable communicable venereal disease? Could you please explain that to me?

Mr. Windom. Sir, the question is raised by many States, and many States have taken action right now, or concerning action to take, as to how to handle that particular problem. I think we will find——

Mr. Dannemeyer. Wait a minute. Dr. Koop in his report to the Nation, at one point in that report, expressly defended the non-reportability of those with the virus to public health authorities.

Mr. Windom. The disease AIDS is reported.

Mr. Dannemeyer. I understand that, sir. But the virus is not?

Mr. Windom. That's right. In some States.

Mr. Dannemeyer. Dr. Koop in his report specifically attempted to defend the non-reportability of those with the virus. Why does he do that? Why do you do that?

Mr. Windom. Well, we are informing our States, and let them make these decisions based upon the evaluation of this condition, in those people who are antibody positive. Some States do report it.

Mr. Dannemeyer. Now you, under Dr. Bowen, you are the head of the Public Health Service in America, aren't you?

Mr. Windom. Yes, sir.

Mr. Dannemeyer. They do what you tell them because the buck stops with you, right?

Mr. Windom. Yes, to an extent. Then it goes on up to Dr. Bowen also. But we just held a conference—we just held a conference——

Mr. Dannemeyer. You made up your mind to make a public policy position that those with the virus should be reportable. You'd recommend that to the people of the country and the States, and they'd probably do it, wouldn't they?

Mr. WINDOM. Well, first the results of the meeting we just sponsored and held 2 weeks ago was dealing with this subject of testing and reporting, and that information will be brought to me on April 1. And we will look at that in great depth, then come forth with the recommendations or decisions based upon that best input from people representing the whole Nation, over 900 people at this important program. So it's through this mechanism that we do make decisions, based upon input from many sources.

Mr. DANNEMEYER. Do you believe sitting here this morning that as a public policy response those with the virus should be reportable?

Mr. WINDOM. I do not feel it should be mandated at this point, sir.

Mr. DANNEMEYER. You don't think it should be mandated?

Mr. WINDOM. At this point, I feel that——

Mr. DANNEMEYER. I'll ask the question again. If by law we require a person with a curable communicable disease to be reported to public health authorities, how in the world do we justify a public health response which does not exact the same requirements for a non-curable communicable venereal disease? How do you explain that?

Mr. WINDOM. Well because there are so many ramifications about this disease that's different from others that we've ever come across, that we have to look at for all these——

Mr. DANNEMEYER. You bet it's different. It's non-curable.

Mr. WINDOM. Right.

Mr. DANNEMEYER. How else is it different?

Mr. WINDOM. Well, in the fact that once it goes through its full-blown stage, it's fatal. And it's rapidly progressively fatal.

Mr. DANNEMEYER. But Doctor, I'll state it this way. If public policy requires we report a curable communicable venereal disease, doesn't it seem logical that we would exact the same requirement for a disease which is not curable?

Mr. WINDOM. Well, that's——

Mr. DANNEMEYER. Human logic would seem to dictate that.

Mr. WINDOM. There is also some evidence, and a feeling that if we did that, there would be a number of instances where that person would never even seek the opportunity to get tested, because it has many other ramifications.

Mr. DANNEMEYER. Now the State of Florida, I mean the States of Colorado, and Idaho and Minnesota in this country reject that argument, don't they? They require that those with the virus be reportable, don't they?

Mr. WINDOM. Yes, sir. Yes.

Mr. DANNEMEYER. Wouldn't you say that every person with the virus today and in next 5 years is going to manifest some impairment of their immune system?

Mr. WINDOM. Well we don't know that, sir.

Mr. DANNEMEYER. Well the French study published about 8 months ago indicated that about 50-70 percent of those with the virus would get AIDS and die, and the balance would all manifest some impairment of their immune system. My point is, you say that some people would not participate if we had mandatory testing.

What I am suggesting is, every person with the virus is going to be in contact with the health care system of this Nation, because they frankly have no place else to go, and at that point they have no place to hide, and when they come into the health care system, isn't it appropriate that we adopt and respond with the normal routine public health response for every communicable disease that has come down the pike in the lab test—last half century, and make it reportable?

Mr. WINDOM. What you're saying is being considered in many, many places today.

Mr. DANNEMEYER. How long is——

Mr. WAXMAN. Gentlemen, the time has expired.

Mr. DANNEMEYER. Wait a minute, Mr. Chairman. You started at 10:24 and quit at 10:36. I started at 10:36 and I think I should be able to go to 10:48, and take 12 minutes just like the Chairman did.

Mr. WAXMAN. Well I'm sorry, I'm sorry, I don't think you've calculated correctly, and I think we've given you the same amount of time, but we'll give you an opportunity in the second round. Mr. Wyden has been waiting patiently, and you have another opportunity.

Mr. WYDEN. Thank you, Mr. Chairman. I just have a couple of questions.

Dr. Roper, in 1987 the cost of AZT in the Medicaid program could reach $50 million, according to your indications. Is that Federal money, or combined State and Federal?

Mr. ROPER. Combined. It's 25-25 roughly.

Mr. WYDEN. In producing that number, Doctor, how many States do you assume are going to cover AZT this year?

Mr. ROPER. We assume that 26 States will immediately cover. They are the ones with so-called open formularies.

Mr. WYDEN. I think all of us on the subcommittee would appreciate for the record, the data and assumptions used by HFCA to estimate the Medicaid related costs of AIDS and AZT?

Mr. ROPER. I'd be glad to provide that, yes.

Mr. WYDEN. For the sake of the record.

Mr. ROPER. Yes.

Mr. WYDEN. Dr. Roper, my second question is, what is the range of poverty that AIDS patients have to reach before becoming eligible for Medicaid?

Mr. ROPER. It's substantial poverty. It varies across the states. States have different levels.

Mr. WYDEN. Well, I know that the Chairman spoke of the Florida situation at a very low level. But I think there are several States that are even well below that. I think one State, it may be Alabama, but I'm not sure, you have to have $88 a month for a family of 2 in order to be eligible.

Mr. ROPER. I don't know the Alabama figures off the top of my head, but substantial poverty in many States is required.

Mr. WYDEN. Should patients have to move from the States with a very low level? From Florida, and if it's Alabama, as I say I don't know, to California to get AZT? Is that what the administration is advocating?

Mr. ROPER. No. We are advocating the States to effectively manage their Medicaid program.

Mr. WYDEN. But what if you're very low income, yet you still don't qualify, in your State. I heard that, I guess it's an old notion, vote with your feet, but clearly people who are in pain and are disabled couldn't possibly do that. It would certainly put an extra burden on the States. What do you do if you're very low income, in a State you're not eligible.

Mr. ROPER. Well the question you pose—it strikes to the heart of a Federally-State operated program, a partnership program. We depend on the voters and the elected officials of the several States to do the right thing by their citizens.

Mr. WYDEN. Well, I think we're all interested in the States doing as much as possible. I'm just concerned that people are going to fall through the cracks as a result of this situation. There may not be any drug services in their State, and they may not be able to move.

The question for both of you that I'd like to ask, deals with whose responsibility is this? Where are the lines between the Federal Government and the States? I think your positions are a little bit different.

I understood Dr. Windom to say that it's unethical to withhold AZT from AIDS patients. That was Dr. Windom's statement to Chairman Waxman. But Dr. Roper has said that's it's not a Federal ethical responsibility. My question is, whose responsibility is it?

Mr. ROPER. I think we as a society have a responsibility to pay for health care services to those who can't afford to pay for them themselves. That includes not only AIDS patients, but patients of whatever malady. And society has that duty. The Federal Government, State Government, local Governments, the private sector, the manufacturers of the drug. It's a responsibility that we all share. The Federal Government is discharging that responsibility primarily through the Medicaid program, as I've said.

Mr. WYDEN. I don't think that's much solace to people in great pain, and agony to say that society in the abstract has a responsibility to do it. We haveto make decisions to try to help alleviate that pain, and make sure they're in the most cost effective manner. I personally think the Federal Government has a more significant role to play in this then all of you do, but that will be a subject for other debates.

Dr. Windom, would you want to comment?

Mr. WINDOM. Yes, sir, Mr. Congressman. This is a early disease process, it's a very devastating one that has aroused the concern of millions of people in this Nation, and we know of many communities where this disease has manifested itself more than others. There's a great deal of community effort, individuals helping the patient through many ways, to show compassion, and concern, and to make their care more available with all the help of many disciplines. So I think it is evident that there is a great deal of humanistic approach to this disease on all levels.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden. The thought that strikes me that when you say society has the obligation to pay for it is that that could be an excuse for no one in society taking the responsibility. It could be an excuse for the Federal Government not to do it, for the States not to do it, for the drug companies to assume that somebody will pay whatever their price will be, and we could easily see large numbers of patients going without this drug which we would all consider an unethical, unacceptable situation. So we're going to have to, it seems to me, monitor this situation very carefully.

Dr. Windom, there are a lot of questions I could ask you about the AIDS problem, and about reporting and testing routine, mandatory, whatever. We are going to hold hearings on these issues at a later date. This is not an issue we're unconcerned about, but I'm going to refrain from getting into those issues at this time, because we have this hearing on this question. But any member can pursue anything they want when they're asked—when they're given the time to pursue questions.

I just don't want you to think that our refraining from going into these questions means that we agree with Mr. Dannemeyer on his point of view, or that we are uninterested in this situation.

Mr. Dannemeyer, do you wish a second round?

Mr. DANNEMEYER. Yes; I do.

Mr. WAXMAN. The gentleman is recognized for 5 minutes.

Mr. DANNEMEYER. Thank you, Mr. Chairman. Dr. Windom, I don't think you were working as head of the Public Health Service of the Federal Government in March of 1985, but I suspect one of the staff persons sitting behind you there can help you with respect to this issue, because it relates to the integrity of the blood supply of this country.

In March of 1985, the Public Health Service of the United States Government took some action in order to protect the integrity of the blood supply and in about March of that year, action was taken with respect to the group that contributed 17 percent of the AIDS' cases, intravenous drug users. That action provided that the group contributing 17 percent of the AIDS cases cannot donate blood; isn't that right?

Mr. WINDOM. An intravenous drug user cannot?

Mr. DANNEMEYER. In the Spring of 1985, statistically speaking, 17 percent of the AIDS' cases came from a group called intravenous drug users, and so from the standpoint of protecting the blood supply of the country, a decision was made that that group that contributed 17 percent of the AIDS' cases, cannot donate blood; isn't that right?

Mr. WINDOM. Yes.

Mr. DANNEMEYER. At the same time, the Public Health Service for the United States Government made a decision with respect to the group that contributed 73 percent of the AIDS' cases, male homosexuals, relating to the integrity of the blood supply. Specifically, the Public Health Service said, and here they differed, if you subjectively consider yourself to be a monogonous male homosexual, there is no restriction on your donating blood at all, but if you subjectively considered yourself to be a polygamous male homosexual, the Public Health Service said you should not donate blood; isn't that right?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. And then in September of 1986, you changed your policy whereby you said, irrespective of whether you classify yourself as a monogonous or polygamous male homosexual, you should not donate blood; isn't that correct?

Mr. WINDOM. Yes.

Mr. DANNEMEYER. Now, the question I have is this; if it is sound public policy to protect the integrity of the blood supply of this country, that the group that contributes 17 percent of the AIDS' cases, intravenous drug users, is told, you cannot donate blood, how do you justify adopting less than an identical stricture with respect to the group that contributes 73 percent of the AIDS' cases, male homosexuals, but to that group, to my knowledge, you have to this date just said, should not donate blood as opposed to cannot donate blood.

How do you justify that?

Mr. WINDOM. Well, because we feel with the testing procedure, that we can test the blood today, too, for those who do give blood beyond which they should not give it, they still offer giving blood. We cannot prove whether they fit that category or not.

Mr. DANNEMEYER. Well, that's interesting. The testing procedure would pertain to whether you are an intravenous drug user or you are a male homosexual; wouldn't it?

Mr. WINDOM. It could; yes.

Mr. DANNEMEYER. So if the blood test is a constant, there must be some other reason why the Public Health Service has not been able to bring itself and say to the group that contributes 73 percent of the AIDS' cases, you cannot donate blood. Can you give me a rationale as to what—why you do that?

Mr. WINDOM. Well, the history, of course, of the IV drug use, had a greater instance of possibility of the spread or the contamination and consequently, looking at the other issue more with the homosexual population and to evaluate just where we stand at that point.

Mr. DANNEMEYER. Now, let's be candid about it. The ELISA test has a false negative in between 4 and 10 percent of the cases; doesn't it?

Mr. WINDOM. Yes, sir.

Mr. DANNEMEYER. In other words, if a test is negative on a proposed blood sample, there is a 4 to 10 percent chance that that blood can contain the virus for AIDS; right?

Mr. WINDOM. That's too high; about 1 percent now.

Mr. DANNEMEYER. Well, it depends on what statistician you rely upon, but I've seen figures on false negatives between 4 and 10 percent. What figures have you seen?

Mr. WINDOM. I think it is 1 to 2 percent.

Mr. DANNEMEYER. Let's take yours, 1 to 2 percent. Don't you believe it is sound public policy considering we are attempting to protect the integrity of our blood supply, for the Public Health Service to say to the group that contributes 73 percent of the AIDS' cases, male homosexuals, you cannot donate blood to the blood supply of this country, just as you have said to the group that contributes 17 percent of the AIDS' cases, intravenous drug users?

Wouldn't that make sound public policy?

Mr. WINDOM. It's something we would have to look at in more depth, sir.

Mr. DANNEMEYER. Well, how long is it going to take you to look at that? Let me give you an example of how this is relevant. Last year, Dr. Windom, the public health in Colorado reported the instance where a donor to the blood supply, and I think it was in May of 1986, showed up negative on the ELISA test and that donor's blood was admitted to the blood supply. That blood ended up being donated from the blood supply to a recipient and the recipient got AIDS. Then that donor came back in August to donate again. That donor tested positive under the ELISA test.

The rationale as to why it was missed at the beginning in May was because it takes about 6 weeks to 10 weeks for the latency period to develop in the human system where antibodies are detected by the antigen.

My point, Dr. Windom, is this; when will the Public Health Service of this country recognize that the current policy on protecting the blood supply of this Nation is defective? Your policy has resulted in that citizen in the State of Colorado getting AIDS, because your policy relating to the people donating blood is defective.

My question is when are you going to straighten it out and say as a matter of public policy that the groups that contribute 17 percent of the AIDS' cases, intravenous drug users, are going to be treated on the same basis as the group that contributes 73 percent of the AIDS' cases, male homosexuals. Those groups should be told, that they cannot donate blood. When will you do that?

Mr. WINDOM. Well, as I mentioned, the first of April we will have a report of that meeting which discussed this very intensively, 2 weeks ago, on the question of blood testing and mandating and to look at that in more detail to see what we should do, because it is a question that is broad based and requires a great deal of input.

Mr. WAXMAN. The gentleman's time has expired.

Mr. DANNEMEYER. In my judgment, you are treating this as a civil rights issue. You and the other members of the Public Health Service, in my judgment, are derelict in your responsibility and if you can't straighten up the public policy health response to this epidemic in America, I think with all due respect, sir, you should be replaced by people who will have that courage to do so.

Thank you, Mr. Chairman.

Mr. WAXMAN. The gentleman's time has expired. What Mr. Dannemeyer has expressed here is nothing new. He has expressed it in other settings and other forums and in complaints to the President himself, as I understand it, there were letters complaining about his own administration.

But just on this blood question, which isn't the subject for debate today but it has been raised, if you have someone coming in to donate blood and they are an intravenous drug user, that can be determined by a medical person at the site where the blood is to be donated. If someone is a homosexual, you are relying on that person's judgment. You have to prove whether that individual is correct or not in the statement that he or she makes, that it is not the case.

The Public Health Service has relied on the fact that you can screen out the blood rather than try to go out and find out whether these individuals are other than what they say they are.

You say, someone comes in to donate blood, you are not to donate blood if you are a homosexual. Isn't that correct?

Mr. **Windom**. We request that if individuals have had sexual relations with another male since 1977, are a category of people who should not donate blood.

Mr. **Waxman**. You tell them don't donate blood. Now, if you are going to require them at the site to go out and investigate further, you are going to have to investigate everybody who comes in. Now, the reason, as I understand it, that you have this particular process, is because you have the ability to then examine the blood.

You tell people not to donate blood and then you screen the blood to see if the virus is in the donated blood and you remove any blood from whatever source. After all, you can have blood with the virus in it from someone who is not a homosexual, who never was aware they were carrying that virus.

I wanted to raise those points, as well, to counter the charges that have been made, that you have not been acting in an responsible way.

That concludes our business before the subcommittee. We stand adjourned.

[Whereupon, at 12:00 p.m., the hearing was adjourned, to reconvene at the call of the Chair.]

[The following letter was submitted for the record:]

American Pharmaceutical Association

STATEMENT ON THE DISTRIBUTION OF THE ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS) DRUG AZIDOTHYMIDINE (AZT)

The American Pharmaceutical Association (APhA) commends the Burroughs-Wellcome Co for its decision to distrubute the new AIDS drug, azidothymidine (AZT), through the traditional drug distribution system that ensures the active participation of pharmacists. Although the AIDS patient will be required to designate a particular pharmacy where he or she will have prescription orders for AZT dispensed, the patient through this system will be assured access to comprehensive pharmaceutical services through the pharmacy of his or her choice.

In the case of AZT, it is particularly appropriate that the traditional physician-pharmacist-patient relationship has been preserved. AZT is a highly toxic drug for which therapy must be individualized for each patient. Further, strict adherence to the prescribed dosage is essential to achieve maximum effect. Consequently, patients on AZT therapy require special counseling, and their therapy must be closely monitored. Pharmacists are especially suited to provide these essential services. Besides special services related directly to their drug therapy, patients on AZT, because of the nature of their disease, often require other community health services, such as hospices and mental health counseling, and pharmacists can refer patients to such services available in their communities.

Pharmacists can also assist patients in dealing with the relatively high cost of AZT therapy. Pharmacists have historically worked with their patients to achieve maximum drug therapy effect at the lowest possible cost, as well as to help identify sources of financial assistance that might be available in the community to help with patients' drug therapy costs. In the case of AZT, pharmacists through their monitoring function can work with patients and physicians to achieve a dosage level that will be effective yet most economical.

In addition to helping tailor therapy to achieve cost savings, pharmacists' traditional methods of determining their fees will also help keep patient costs low. Although pharmacists will be assuming significant financial risks and inventory carrying costs related to stocking AZT, the fees which pharmacists will receive, besides recovering their actual costs for the drug product, will relate primarily to their provision of the counseling, monitoring and other pharmaceutical services that they will be providing to the patient. Therefore, it si clear then that patient cost estimates cannot and should not be based upon percentage markups on the wholesale price of the drug charged by the manufacturer. Although the actual professional fee received by pharmacists will vary from pharmacist to pharmacist, all pharmacists obviously are entitled to receive a reasonable professional fee for the services they provide in supplying the drug. However, if compared with a percentage of wholesale cost, that fee likely will be quite small.

As experience is gained on the distribution of AZT, APhA has offered to further work with Burroughs-Wellcome to make any adjustments in the distribution system that would assure that it works even better to help the AIDS patient.

AIDS ISSUES
AIDS and Minorities

MONDAY, APRIL 27, 1987.

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Houston, TX.

The subcommittee met, pursuant to notice, at 9:30 a.m., in Moot Court Room of the Law School at Texas Southern University, Houston, Texas, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. The meeting will come to order.

We will speak as loudly as we can. We want to welcome you to this subcommittee meeting hearing of the Health and Environment Subcommittee of the Energy and Commerce Committee of the House of Representatives. This subcommittee has held over a dozen hearings on the epidemic of Acquired Immune Deficiency Syndrome or AIDS. Most have been on the stubborn refusal of the Reagan administration to heed the warnings of its own best health and medical experts. Some have been on models of clinical care for AIDS patients. Some have been on the need to develop new therapies for the disease.

Today's hearing will deal with all of these issues at once. But today's hearing is also to bring to public attention a side of the epidemic that has been largely unaddressed: The disproportionate dangers that AIDS poses for minorities in America.

I have argued on many occasions that had AIDS first appeared among members of the Chamber of Commerce, the Federal response to the disease would have been much more urgent and much more comprehensive. Since the disease was first recognized among gay men, however, the Reagan administration dealt with it as business as usual.

This neglect of gay men who were ill is now matched by the administration's unwillingness to recognize the particular problems of AIDS among minority groups, both gay and straight. While Black Americans represent about 12 percent of the population of the Nation, they represent 25 percent of the confirmed cases of AIDS. While Hispanic Americans represent 7 percent of the population, they make up 14 percents of the cases of AIDS.

These numbers are complex. They involve drug abuse and sexual activity. They are tied to a variety of problems in minority access to health care, education and employment.

But clearly above and beyond these complexities, these statistics point out that there is a special need for the public health agencies of Federal, State, and local governments to provide AIDS education and clinical care services that reach Black and Hispanic Americans. Educational programs for white gay men may never reach Hispanic gay men. Counseling programs for white pregnant women may be inaccessible to Black pregnant women.

The Reagan Revolution in government services has hit minority groups particularly hard. The AIDS epidemic will make these years of neglect even more devastating and will be fatal for many Black and Hispanic people.

I hope that with today's hearings, we will remove some of the blinders that surround observers of AIDS and finally conclude that AIDS is a crisis for all Americans Hispanic, Black and white, heterosexual and homosexual, young and old. Once that occurs, we will be able to address the disease as a disease and not as a curse. We will be able to care for all sick people regardless of their race or their income. And I hope we will be able to bring together a Nation that is becoming frightened and torn over the epidemic.

I want to thank Congressman Mickey Leland, who has invited us to come to this meeting, today, and to hold this hearing. Congressman Leland is a very active member of the Subcommittee on Health, has been involved in our hearings and activities in the AIDS area, as well as in many other health issues. And, through his leadership, we are trying to deal with these very pressing problems at a time when we are having a lot of trouble from the failure of the cooperation of many of the administration to recognize the realities.

We hope this hearing will aid both of us in fighting for more Federal efforts to combat the AIDS epidemic and to make sure that those Federal efforts are targeted and clear and coherent from a public health point of view.

And I want to recognize at this time, Congressman Leland.

Mr. LELAND. Thank you very much, Mr. Chairman. Let me thank you for your very quick and ready response to the invitation to come and hold this hearing here in my city, in my district, at my alma mater.

A few years ago, the Gay Political Caucus invited me to a "town hall" meeting and introduced me to the very severe and critical problem that afflicts Houston. This problem, of course, of AIDS.

I was involved through the committee's work and activities with the issue of AIDS, but had never realized to what extent or the magnitude of the problem that existed in my own city. I guess, to some extent, I was as guilty as some of our so-called city leadership with my ignorance about the prominence of this very serious, this very serious affliction of our city and our country.

I am most pleased, however, that indeed there are those of you, Mr. Chairman, in the Congress, who would take the kind of fervent leadership to not only address the problem of how it is that we cure AIDS, but also how it is that we prevent AIDS.

It is becoming more and more apparent, now, that the homosexual community is not the only community that has been afflicted with this disease. The gay community, the gay and lesbian communities are communities that indeed we have to guard in terms of their human rights and their human ailments, if you will, and we cannot push them aside. But, at the same time, and I do not want to demean the interest of doing just that, but at the same time, I would like to expand this sphere of discussion in order that we can address the very critical problem of AIDS that is growing amongst heterosexuals and, particularly, amongst minorities, too. I think maybe with working in coalition together with those all who are afflicted, we can finally realize some true solutions to the problem.

Since AIDS was first targeted as a specific disease in 1981, it has received a tremendous amount of public attention. Unfortunately, the general public continues to think of AIDS as a disease of homosexual white males. As a result, one aspect of the epidemic has been largely overlooked. AIDS cases occur nearly three times more frequently among Black and Hispanic men than among white men, as was alluded to by our chairman. And the incidence among Black and Hispanic women and children compared to whites is even higher. Moreover, recent studies indicate that AIDS will continue to spread at much higher rates among Blacks and Hispanics than among whites. If we are serious about developing a game plan with which to win this war against AIDS, these sobering statistics must be taken into consideration.

In order for our actions to be effective, we must aggressively pursue answers to such difficult questions as: Why does AIDS occur more frequently amongst minorities than whites. And why is this disease increasing in the heterosexual community?

We already have many hints as to answers to some of these questions. For instance, in the white community, AIDS has spread primarily through male homosexual contact and women having contact with bisexual men. Among Blacks and Hispanics, however, AIDS is spread primarily as the result of intravenous drug abuse and heterosexual contact. This pattern is partly due to the disproportionately large number of Black and Hispanic IV drug users in areas most affected by the AIDS epidemic.

As a matter of fact, 62 percent of minorities acquiring AIDS through heterosexual contact have reported sexual contact with an IV drug user. Since most of the women with AIDS are Black and Hispanic, it is not surprising that most children with AIDS are also Black and Hispanic, estimated to be about 80 percent of the victims afflicted with AIDS.

AIDS affects our entire society. Therefore, we must all work together to address this problem. Black and Hispanic organizations have a unique opportunity and obligation to become educated about AIDS and how to stop its further spread in our communities.

Of course, the development of an effective vaccine and treatment must remain a high priority. But until a vaccine and treatment are discovered, prevention programs are our only remedy.

Mr. Chairman, today's hearing is an integral and critical aspect of any prevention remedy: Education. In conclusion, Mr. Chairman, I am pleased that these panel members will help educate all of us about the impact of AIDS beyond the homosexual community, in general. And I would like to again reiterate that that does not demean the importance for us to pursue how it is that we can protect our homosexual community against this very dire disease.

Mr. Chairman, let me at this time, if I may, thank the President of the Texas Southern University for not only his participation, which is to ensue, and I see that he is here, for allowing us to hold this hearing here.

We would like to thank Gene Harrington, who we know facilitated the opportunity for us to participate in this setting at the Moot Court of the Thurgood Marshall Law School. Let me also thank the Chicano law students as well as the Black Law students who facilitated the welcoming banners that we see and the refreshments that we were able to get before the hearing and for all of those who have participated here in the City of Houston to help put this incredible hearing and this landmark hearing, I might add, Mr. Chairman, on here in the City of Houston, at Texas Southern University.

[The opening statements of Hon. Mickey Leland and Hon. Jack Fields follows:]

Statement of Hon. Mickey Leland

Mr. Chairman, I want to take this opportunity to thank you for holding this hearing here in our City of Houston and for your focus on the problem of AIDS both in and beyond the homosexual community.

Since AIDS was first targeted as a specific disease in 1981, it has received a tremendous amount of public attention. Unfortunately, far too many members of the general public continue to think of AIDS as a disease of homosexual males. And many people continue to thing of AIDS as a disease which predominately affects the white community. As a result, one aspect of the epidemic has been largely overlooked: AIDS cases occur nearly three times more frequently among Black and Hispanic men than among white men. And the incidence among Black and Hispanic women and children compared to whites is even higher. Moreover, recent studies indicate that AIDS will continue to spread at much higher rates among Blacks and Hispanics than among whites. And since most of the women with AIDS are Black and Hispanic, it is not surprising that most children with AIDS are also Black and Hispanic. If we are serious about developing a game-plan to win the war against AIDS, these sobering statistics must be taken into consideration.

In order for our actions to be effective, we must aggressively pursue answers to such difficult questions as: Why does AIDS occur more frequently among minorities than whites? And why is this disease increasing in the heterosexual community?

We already have many hints as to the answers to some of these questions. For instance, in the white community, AIDS has spread primarily through male homosexual contact and women having contact with bisexual men. Among Blacks and Hispanics, however, AIDS is spread primarily as the result of intravenous drug abuse and heterosexual contact. This pattern is partly due to the disproportionately large number of Black and Hispanic I.V. drug abusers in areas most affected by the AIDS epidemic. As a matter of fact, 62 percent of minorities acquiring AIDS through heterosexual contact have reported sexual contact with an I.V. drug abuser.

AIDS affects our entire society; therefore, we must all work together to address this problem. Black and Hispanic organizations have a unique opportunity and obligation to become educated about AIDS and how to stop its further spread in our communities.

Of course, the development of an effective vaccine and treatment *must* remain a high priority; but until a vaccine and treatment are discovered, prevention programs are our only remedy. In my view, an effective prevention program must include certain features that have not yet received much public or media attention. These include: (1) targeted outreach risk reduction programs for minority populations; (2) programs that are sensitive to cultural and language needs; (3) improved access to, and utilization of, health services to minority populations; (4) coordinated Federal, State, and local prevention activities; and (5) technical assistance for community groups.

Mr. Chairman, today's hearing is an integral and critical aspect of any prevention remedy—education.

In conclusion, Mr. Chairman, I am pleased that these panel members will help educate all of us about the impact of AIDS beyond the homosexual community, in general, and in minority communities in particular. I look forward to hearing their testimony on how best to address this devastating epidemic.

STATEMENT OF HON. JACK FIELDS

Thank you, Mr. Chairman. Mr. Chairman, I want to commend you and my colleague from Houston, Congressman Mickey Leland, for conducting this hearing today here in Houston. Acquired Immune Deficiency Syndrome, or AIDS, as it is commonly known, is the most pressing public health problem with which this country is faced today. It certainly merits considerable attention by our society.

This deadly disease also merits considerable attention in Houston and Harris County. Latest figures show that Harris County has logged 1,027 cases of AIDS. This is the fourth highest tally in the country.

The State of Texas also has the fourth highest State total. There have been 2,138 confirmed cases of AIDS in Texas; almost half of that total has been in the Houston area. In Texas, there have been 1,325 deaths.

If there are no significant breakthroughs in the treatment and prevention of AIDS, by 1991, 240,000 people in Texas will have been exposed to AIDS; 16,200 of those will be confirmed cases; and of those 16,200, about 11,000 will have died from AIDS.

Texas Commissioner of Health Robert Bernstein has predicted 60,000 cases of AIDS in Texas by 1997. Certainly it was an understatement when U.S. Surgeon General C. Everett Koop told a Joint Session of the Texas Legislature that "You've got a big problem in Texas." This is one situation that I sincerely wish weren't "Texas-sized."

Nationally, there have been 33,997 confirmed cases of AIDS; of those cases, 19,658 people have died. Almost a year ago the U.S. Department of Health and Human Services projected that there would be about 196,000 confirmed cases of AIDS by the beginning of 1991, with another 74,000 diagnosed during 1991. Health and Human Services also predicted that 125,000 people will have died from AIDS by the beginning of 1991, with 54,000 more deaths during the year.

These are monumental figures. Perhaps the immensity of the problem can best be appreciated by comparing it with the tragedy that occurred when polio was epidemic 40 years ago.

Between 1943 and 1956, 400,000 people were infected with polio. Since AIDS was introduced into the United States, probably in 1976, experts estimate that *at least* 1.5 million people have been infected with, or are carriers of, the virus.

Of the 400,000 people who were infected with polio, 22,000 died during the period 1943–1956. As I mentioned earlier, nearly 20,000 have already died from AIDS. With AIDS, I am afraid, the worst is yet to come.

I am sure everyone has heard all of these staggering numbers before. But I, and others, recount them to impress upon all of us that this communicable disease is the severest public health problem any of us have faced, or are likely to face, in our lifetime. While more people may die from cancer, heart disease and stroke this year and next, they are not contagious diseases. The specter of contagion is what sets AIDS in a class by itself.

With that caveat firmly in mind, we must all concert our efforts to rid our society of this deadly disease. When I say we, I mean the local, State and Federal levels of government, as well as the private sector. We all have a responsibility to contribute to the provision of adequate resources to effectively deal with AIDS.

We also must be courageous enough to take the appropriate public health measures which will curtail needless suffering and death. This may require some tough decision-making; but, it will be necessary.

Mr. Chairman and Congressman Leland, I hope we can work together on measures which adequately and appropriately address the public health disaster of Acquired Immune Deficiency Syndrome.

Thank you, Mr. Chairman.

Mr. WAXMAN. I would like to call forward Dr. Robert Terry, president of Texas Southern University to make a presentation to the subcommittee. As Dr. Terry approaches, I want to let him know how much we do appreciate the fact that we are holding this meeting here today and we appreciate your hospitality in allowing us to meet in the Moot Court.

It is a long time since I was in a Moot Courtroom, not since I was at UCLA Law School, and I was not up on this side of the room when I was last in a Moot Court setting. But this feels much better up here than down there.

And Dr. Terry, now you have your turn to be down there.

Mr. LELAND. Mr. Chairman, before the president speaks, I see that the Dean of the Law School is also here, Dean Douglas; and we want to thank him, too, for this program.

STATEMENT OF ROBERT J. TERRY, PRESIDENT, TEXAS SOUTHERN UNIVERSITY

Mr. TERRY. Thank you, Mr. Chairman, and good morning.

I am Robert J. Terry, president of Texas Southern University. I am a biomedical scientist. I am honored to welcome the US House of Representatives Subcommittee on Health and the Environment to our campus. I believe it is especially fitting that these hearings focusing on AIDS and its impact upon minorities are being held in the Thurgood Marshall School of Law.

While AIDS is a major medical and social problem, effecting American society in general, it is especially devastating to minority communities, women and children. The following statistics are provided by the Centers for Disease Control in the United States. In the United States, Black people make up a disproportionate number of persons with AIDS. Thirty-eight percent of all of those with AIDS in the United States are minorities. And 87 percent of women with AIDS are women of color. Ninety-one percent of all children with AIDS are non-white. And 60 percent of those with AIDS in Newark, New Jersey are heterosexual Black people. In Washington, DC, 50 percent of those who have AIDS are non-white heterosexuals. And in New York City, nearly one-half of the AIDS cases are heterosexual and 80 percent of these are Black or Hispanic.

Most heterosexually infected persons with AIDS in the United States have been Black or Hispanic women. Heterosexual women who are not drug abusers have the highest rate of increase than any group. As a special purpose institution of higher education, Texas Southern University is an appropriate site for these hearings. The Thurgood Marshall School of Law is one of the leading non-medical institutions in the country that is devoting its attention to AIDS and its impact upon people of color.

The Houston Mayor's Task Force on AIDS, the AIDS Foundation in Houston, the Texas Human Rights Foundation and the Association of American Law School's Section Dealing with AIDS have all had the benefit of our law faculty input. Our Law Library has one of the most complete collection of AIDS' discrimination materials and we have the most complete AIDS' clipping service in the city.

In addition, our law faculty was instrumental in conjunction with the Clark Reed Foundation in setting up the AIDS Legal Hotline which provides legal assistance to persons being illegally discriminated because of AIDS and AIDS-related complex, or HIV serially positive status.

In September, the Law School will host a national conference on AIDS, Minorities and the Law, which will convene legal experts from throughout the country to discuss the major legal issues AIDS presents.

I believe the reception you have received this morning from the administration, from the faculty and student body is testimony to the dedication of our institution in insuring that the special problems that AIDS poses to people of color are adequately addressed.

I again welcome you and wish the hearings a success. Thank you very much.

Mr. WAXMAN. Thank you very much, Dr. Terry.

I want to thank you very much, again, for having us here. Our subcommittee has been the most active in dealing with the AIDS crisis in the Congress. We have held a number of hearings. And this is the second hearing outside of Washington. The first was in Los Angeles in 1981 when we did not even know the word, "AIDS." We had first received reports of a disease called Kaposi's Sarcoma, which is a rare form of cancer. And, suddenly, it was occurring among gay men in the United States in very small numbers.

Well, now, after all of these years, we have discovered AIDS. We have seen over 30,000 Americans come down with AIDS. We have seen the statistics of the number of people that will get this disease in the coming years, which is very, very frightening, indeed. And, as we look at the statistics for Houston, they are among the most frightening.

As of April 13, Texas had the fourth highest number of cases in the country, behind New York, California and Florida. Total cases were 2,142. Also, as of April 13, Houston had the fourth highest number of cases among cities in the United States. And we realize that the problems here are going to be the kind of problems that other cities, unfortunately, will go through in the years ahead. So, we want to learn what we can from the experience here in Texas with all those people who have AIDS and with special emphasis on special groups, minority groups, particularly, that are afflicted and how, how they ought to be handled in ways that will be more sensitive to the differences in the population.

I thank you very much for greeting us and for hosting us.

To give us a background about the AIDS disease, I would like to call forward to testify as a panel: Dr. J. Michael Lane, Director, Center for Prevention Services, Centers for Disease Control, Atlanta, GA; Dr. Mathilde Krim, Associate Research Scientist, St. Luke's-Roosevelt Hospital Center and Columbia University, and Founding Chair of the American Foundation for AIDS Research; and Dr. James Haughton, Director, City of Houston Department of Health and Human Services. If the three of you would please come forward in these seats where there are microphones.

We are pleased to welcome the three of you to this hearing, today. We have prepared statements that you presented to us and those prepared statements will be made part of the record, in full: but what we would like to ask you and all other witnesses today is to try to summarize your testimony in no more than 5 minutes. We will have to try to ask everyone's cooperation. As difficult as it is sometimes to say all that you want to say in 5 minutes, but for us to have the full opportunity for questions and answers and to hear all of the witnesses and to keep with all the schedules that we are trying to juggle today.

So, we are going to use a timer which will ring at the end of 5 minutes to let you know that the time has expired and we would like to ask at that point that the witnesses give us a summary sentence and conclude.

Why do we not start with Dr. Lane, if we might.

STATEMENTS OF J. MICHAEL LANE, DIRECTOR, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MATHILDE KRIM, ASSOCIATE RESEARCH SCIENTIST, ST. LUKE'S-ROOSEVELT HOSPITAL CENTER AND COLUMBIA UNIVERSITY, AND FOUNDING CHAIRWOMAN, AMERICAN FOUNDATION FOR AIDS RESEARCH; AND JAMES G. HAUGHTON, DIRECTOR, CITY OF HOUSTON DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. LANE. Thank you, Mr. Chairman. I am Dr. J. Michael Lane, Director of the Center for Prevention Services at CDC. And I am pleased to represent CDC at this hearing.

AIDS., as you know, is the Nation's No. 1 public health problem, with nearly 35,000 cases and nearly 20,000 deaths having been reported since 1981. The largest number of cases have been concentrated in certain areas such as New York, San Francisco, Los Angeles, here in Houston, and Miami. But AIDS has been represented in every State in the Union. In 1985, AIDS became No. 11 leading cause of potential years of life lost before the age of 65 and provisional data indicate that in 1986, it moved up to the eighth spot.

Blacks and Hispanics are being disproportionately affected by this epidemic. Of the more than 34,000 cases of AIDS reported to CDC as of April 20, 24 percent were Black and 14 percent Hispanics, whereas these groups represent only 12 and 6 percent, respectively, of the U.S. population.

Even more racial differences are seen for certain groups of AIDS patients. For examples, Blacks and Hispanics account for 72 percent of all heterosexual adults with AIDS and 79 percent of all children with AIDS. Approximately two-thirds of Black and Hispanic AIDS patients are residents of New York State, New Jersey and Florida.

The great majority of adults with AIDS can be placed in one or more transmission categories: homosexual and bisexual men, intravenous drug abusers, hemophilia patients, transfusion recipients and the heterosexual partners of persons in these groups. Blacks and are over-represented in all of these categories except for hemophiliacs. Particularly effected are Black and Hispanics IV drug abusers, their sexual partners and children.

There are no studies that suggests that Blacks or Hispanics are physiologically more susceptible than whites to infection with the AIDS virus or to the development of AIDS once infected. As with other public health problems, there are undoubtedly many socioeconomic and other factors that influence the incidence of AIDS. For example, increased rates of AIDS in Blacks and Hispanics probably reflect behaviors that place them at increased risk for AIDS virus infection. Some of the differences in the national rates of AIDS between minorities and whites may also be a reflection of the racial and ethnic distribution of high AIDS incidence areas.

I would like now to touch on some of the things that we are doing or will be doing at CDC to address this important problem. Our major efforts to prevent and control AIDS in minority populations are found in the health education/risk reduction aspects of the prevent projects that we have been funding in all States, territories and selected metropolitan areas. In these 55 programs already underway, 15 have activities aimed at their Hispanic populations and 21 have targeted the information and education services to the Black communities.

We recently published new guidelines governing the criteria for continuation of these projects. We established a requirement that applicants State and local health departments must recognize in their applications the problem of AIDS minorities and describe education and outreach plans designed to reach persons at risk in minority communities. Of the 58 cooperative agreements recently received for AIDS prevention support, the overwhelming majority indicated plans to provide a minority health component in their AIDS health education/risk reduction efforts.

The Public Health Services, through its AIDS Executive Task Force, coordinates the AIDS prevention and control efforts of the operating agencies, including CDC. The Director of the Office of Minority Health is a member of that task force. I might add that there is also a person at CDC whose sole responsibility is related to the problem of AIDS and minorities.

The CDC has funded and will continue to support innovative AIDS risk reduction projects with Narcotic and Drug Research, Incorporated of New York City and Beth Israel Medical Center in the same locality. These projects are targeted to minorities and will test prevention techniques among drug abusers.

The CDC also supports a three-part AIDS Community-based Demonstration Project in the New York City area which is focusing on AIDS prevention among street addicts, condom usage among women in areas with high prevalence of both AIDS and drug abuse, and prevention of infection among couples when one partner is on methadone maintenance. This project focuses on changing behaviors that are found to a greater degree in minority populations. Projects in Chicago and in Long Beach, California, also have components which focus on minorities.

The CDC will soon announce the availability of funds for one to three pilot demonstration projects to prevent the perinatal transmission of AIDS virus infection. Nearly 90 percent of children who have acquired AIDS through perinatal transmission are Black or Hispanic. Therefore, these projects will focus on individuals from minority communities and particularly on people who use IV drugs or who are the spouses or sexual partners of drug abusers.

Additionally, backstopping all of these efforts, is the AIDS Information/Education Plan to prevent and control AIDS in the United States. Mr. Chairman, I know you know of this plan and I am simply going to allude to it for the record.

We realize that the problem of AIDS in minority communities will require some additional targeted efforts. This summer, on behalf of the Public Health Service, CDC will hold a national conference to solicit the advice and assistance of experts from minority organizations across the Nation to address the problem of AIDS in minority populations. This conference is tentatively scheduled for August 1987 to take maximum advantage of the information that can be shared and we hope this conference will help us in developing policy for the future. Thank you, sir.

[Testimony resumes on p. 77.]

[The statement of Mr. Lane and attachment follow:]

STATEMENT OF

J. MICHAEL LANE, M.D., M.P.H.
DIRECTOR
CENTER FOR PREVENTION SERVICES
CENTERS FOR DISEASE CONTROL
PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, I am J. Michael Lane, Director of the Center for Prevention Services, Centers for Disease Control (CDC). I am pleased to represent CDC in addressing the issue of AIDS in minorities.

AIDS is the Nation's number one public health problem with 34,513 cases and 19,938 deaths having been reported since 1981. To date, the largest number of cases have been concentrated in certain areas such as New York City, San Francisco, Los Angeles, Houston, and Miami. But AIDS is also a national problem, with cases having been reported in every State of the Union. In 1985, AIDS became the eleventh leading cause of potential years of life lost before the age of 65, and provisional data indicate that in 1986 it moved up to the eighth spot.

Although there does not appear, based on data currently available, to be a physiological basis for a higher incidence of AIDS in minorities, there is no doubt that blacks and Hispanics are being disproportionately affected by this epidemic. Of the 34,513 AIDS patients reported to the CDC as of April 20, 1987, 24% were black and 14% were Hispanic, whereas these groups represent only 12% and 6%, respectively, of the U.S. population. An additional 1% of cases occurred in other minority groups and in individuals of unknown race. The overall cumulative incidences for AIDS in black and Hispanic adults - that is, the number of cases per million population in these racial/ethnic groups - are three times that for white non-Hispanic persons.

Even more marked racial differences are seen for certain groups of AIDS patients. For example, blacks and Hispanics account for 72% of all heterosexual adults with AIDS, and 79% of all children with AIDS. Approximately 2/3 of black and Hispanic AIDS patients are residents of New York State, New Jersey, and Florida as compared with only 1/3 of white patients.

As you know, the great majority of adults with AIDS can be placed in one or more transmission categories: homosexual and bisexual men, intravenous (IV) drug abusers, hemophilia patients, transfusion recipients, and the heterosexual partners of persons in these groups. Blacks and Hispanics are overrepresented in all of these categories, except for the category of hemophilia patients. Particularly affected are black and Hispanic IV drug abusers, their sexual partners, and their children. It is also of note that in male AIDS patients who have had sexual contact with other men, black and Hispanic men are more likely to be bisexual than white men, most of whom are exclusively homosexual. These bisexual men can infect their female sexual partners with the AIDS virus and, in turn, these women can infect their newborn children.

The data I have presented thus far deal only with reported AIDS cases. However, similar results are seen when we examine data on the prevalence of infection with the AIDS virus in certain population groups. Again, blacks and Hispanics are disproportionately affected. For example, the U.S. Department of Defense has tested over 700,000 military recruit applicants for evidence of AIDS virus infection. Rates of infection in black and Hispanic applicants have been 5 and 3 times the rate in white applicants, respectively. Even more striking are racial differences in infection rates seen for volunteer blood donors. In a study CDC has conducted with American Red Cross Chapters in Los Angeles, Atlanta, and Maryland, infection rates in black and Hispanic donors were 15 and 5 times the rate in white donors, respectively. Although neither military recruit applicants nor volunteer blood donors represent the general population, these data support our belief that AIDS virus infection is more common in blacks and Hispanics than whites.

As I mentioned earlier, there are no studies that suggest blacks or Hispanics are physiologically more susceptible than whites to infection with the AIDS virus or to the development of AIDS once infected. As with other public health problems, there are undoubtedly many socioeconomic and other factors that influence the incidence of AIDS. For example, increased rates of AIDS in blacks and Hispanics probably reflect behaviors that place them at increased risk for AIDS virus infection. Blacks and Hispanics may have higher rates of IV drug abuse than other persons. In a survey of heroin abuse treatment facilities conducted by the National Institute of Drug Abuse (NIDA) in 1981, 63% of clients were black or Hispanic. In proportion to their numbers in the population, blacks and Hispanics were 9 and 8 times more likely, respectively, to be clients than whites. Some of the difference in the national rates of AIDS between minorities and whites may also be a reflection of the racial and ethnic distribution in high AIDS incidence areas.

Even within AIDS risk groups, blacks and Hispanics may be at increased risk. In three separate studies of AIDS virus infection in IV drug abusers, infection rates were approximately three times higher in blacks and Hispanics than in whites. Although the reasons for the difference are unclear, one possible explanation could be that persons tend to share needles with members of their own racial/ethnic groups. Socioeconomic factors also contribute to needle-sharing. These factors would lead to the non-uniform spread of the AIDS virus among IV drug abusers.

I would like now to share with you some of the things we are doing or will be doing at CDC to address this important problem. Our major efforts to prevent and control AIDS in minority populations are found in the health education/ risk reduction aspects of the prevention projects that we have been funding in 55 States, territories, and selected metropolitan areas. In these programs already underway, 15 have activities aimed at their Hispanic populations and 21 have targeted information and education services to black communities. Most of these activities to date have focused on fully identifying the AIDS problem in each locality, including an assessment of the extent of needle-sharing locally. Data suggest that needle-sharing practices vary remarkably around the country, and may be a reasonable predictor of the potential for infection among IV drug users. Survey results will guide each community's AIDS education strategy.

We recently published new guidelines governing the criteria for continuation of these projects. We established a requirement that applicants--State and local health departments--must recognize in their applications the problem of AIDS in minorities and describe education and outreach plans designed to reach persons at risk in minority communities. Of the 58 cooperative agreements recently received for AIDS prevention support, the overwhelming majority indicated plans to provide a minority health component in their AIDS health education/risk reduction activities. Those who did not will be receiving assistance from CDC in developing a minority component. Some specific examples of the approaches being used might be of interest. Baltimore and New Jersey are using ex-addicts to reach minority street addicts. Additionally they will hire a full-time health educator to focus on minorities and will enter into a contract with the Haitian Council to provide health education/risk reduction messages to this important minority group. Ohio included black community leaders in planning and delivery of health education/risk reduction messages. Michigan included a complete set of measurable objectives targeted to their minority populations. Georgia has entered into a contract with the Morehouse School of Medicine to provide educational seminars for the minority community. Philadelphia will contract with BEBASHI (Blacks Educating Blacks About Sexual Health Issues) to target testing to the black community and to provide training for black community educators. Los Angeles County has funded two Hispanic organizations to provide family-oriented AIDS education and raise AIDS awareness among Hispanic youth.

AIDS Prevention Programs must work closely with the organized segments of the minority communities and develop plans which have the minorities themselves delivering most of the information and messages regarding AIDS risk reduction, through appropriate messages concerning abstinence and safer sex, through drug abuse counseling, and through serologic testing for the presence of HIV infection. CDC is communicating this message to the States. This aspect of the program will more fully mature during FY 1987 as the dimensions of the problem become known, and relationships with minority community organizations become stronger.

The Public Health Service, through its AIDS Executive Task Force, coordinates the prevention and control efforts of the operating agencies. The Director of the Office of Minority Health is a member of that Task Force. Effective AIDS education is critical, but it must complement efforts to stop drug abuse altogether. To ensure that close communications are maintained between the CDC and NIDA to coordinate their AIDS control efforts, our agencies have entered into a formal agreement. NIDA has taken major responsibility for activities to control the spread of HIV by focusing on increasing recruitment of IV drug abusers into treatment and educating IV drug abusers regarding AIDS risk reduction. The CDC focus is on ensuring that its grantees provide an appropriate array of educational and public health outreach services for minorities. Both agencies are pursuing practical research to get risk reduction messages across to individuals in the minority communities.

CDC has identified an individual within its newly established Office of the Deputy Director for AIDS to serve as liaison with NIDA, and NIDA has a comparable position. I might add that there is also a person at CDC whose sole responsibility is related to the problem of AIDS in minorities. Additionally, CDC staff responsible for training personnel in the States about HIV antibody test counseling have maintained communications with the NIDA Community Research Branch which is coordinating similar training for counselors who work in drug abuse treatment facilities.

CDC has funded and will continue to support Innovative AIDS Risk Reduction projects with Narcotic and Drug Research, Inc., of New York City and Beth Israel Medical Center in the same locality. These projects are targeted to minorities and will test prevention techniques among drug abusers.

CDC also supports a three-part AIDS Community-based Demonstration Project in the New York City area which is focusing on AIDS prevention among street addicts, condom usage among women in areas with high prevalence of both AIDS and drug abuse, and prevention of infection among couples when one partner is on methadone maintenance. This project focuses on changing behaviors that are found to a greater degree in minority populations. Projects in Chicago and Long Beach also have components which focus on minorities.

CDC will soon announce the availability of funds for 1 to 3 pilot demonstration projects to prevent the perinatal transmission of AIDS virus infection. As I pointed out earlier, nearly 90% of children who have acquired AIDS through perinatal transmission are black or Hispanic. Therefore, these projects will focus on individuals from minority communities, and particularly on people who use IV drugs or who are the spouses or sexual partners of such persons. These pilot projects will probably occur in areas with a high morbidity of AIDS in children. The intention is to develop data to better understand the problem and a methodology for preventing perinatal AIDS which can be used to refine and improve programs across the country.

This year CDC is initiating an AIDS school health program. The program is a mix of technical and financial assistance to existing education agencies and organizations, designed to help school and college-aged youth receive information about AIDS and how to prevent infection with the virus. CDC will be funding cooperative agreements with about 10 State education agencies and 12 local education agencies in States and cities that have reported high numbers of cases of AIDS. These projects also require special attention in meeting minority health education needs.

We will also provide funds to three local education agencies and one State agency to establish training and demonstration centers for assisting other State and local education agencies in the establishment of effective and appropriate AIDS educational strategies. Among other things, these centers will address how to implement effective AIDS education with consideration of cultural differences.

To reinforce the State and local efforts, two cooperative agreements will be established with national minority organizations to help increase the accessibility and effectiveness of AIDS education. We hope that these organizations will be able to influence the minority community and especially those organizations that serve the interest and educational needs of Black and Hispanic youth.

Additionally, backstopping all of these efforts is the AIDS Information/Education Plan to Prevent and Control AIDS in the U.S. A copy of this Plan will be provided for the record. Included in the Plan is the national public information campaign that is being developed, which will have minority aspects, and the national Clearinghouse system which is under development. This latter activity is an effort to establish a network of existing AIDS Clearinghouses, and to provide a mechanism for effectively channeling information to the public through State and local organizations. One aspect of the project will be the identification of culturally sensitive materials that can be used for reaching minority populations.

However, we realize that the problem of AIDS in minority populations will require some special targeted efforts. This summer on behalf of the Public Health Service, CDC will host a national conference to solicit the advice and assistance of experts from minority organizations across the Nation to address the problem of AIDS in minority populations. This conference is tentatively scheduled for August 1987 to take maximum advantage of the information which will be shared at the Third International Conference on AIDS during June in Washington, D.C. The conference on AIDS among minority populations is being designed to raise the awareness of Federal, State and local health education and drug abuse agencies that serve the needs and interests of minority populations about (1) the extent of AIDS and HIV infection, and (2) the prevalence of and factors influencing behaviors that increase the risk of AIDS and HIV infection among minority populations. It will include discussions of actions that should be taken by Federal, State and local health education and drug abuse agencies, as well as organizations that serve minority populations to help reduce the spread of HIV infection among those populations. Through this meeting, we hope that leaders in the minority community will become more aware of programs and resources that are currently available, that groundwork can be laid for more effective involvement of minority organizations in State and local AIDS prevention efforts, and lastly that we will gain new insights into how to assist minority individuals who are at risk of becoming infected.

I will be happy to answer any questions you may have.

AIDS WEEKLY SURVEILLANCE REPORT[1] - UNITED STATES
AIDS PROGRAM, CENTER FOR INFECTIOUS DISEASES
CENTERS FOR DISEASE CONTROL
APRIL 20, 1987

UNITED STATES CASES REPORTED TO CDC

A. TRANSMISSION CATEGORIES[2]

	MALES				FEMALES				TOTAL			
	Since Jan 1		Cumulative		Since Jan 1		Cumulative		Since Jan 1		Cumulative	
ADULTS/ADOLESCENTS	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)
Homosexual/Bisexual Male	3677	(73)	22411	(71)					3677	(68)	22411	(66)
Intravenous (IV) Drug Abuser	569	(11)	4476	(14)	163	(45)	1170	(50)	732	(14)	5646	(17)
Homosexual Male and IV Drug Abuser	363	(7)	2607	(8)					363	(7)	2607	(8)
Hemophilia/Coagulation Disorder	53	(1)	292	(1)	1	(0)	8	(0)	54	(1)	300	(1)
Heterosexual Cases[3]	85	(2)	643	(2)	104	(28)	666	(29)	189	(3)	1309	(4)
Transfusion, Blood/Components	98	(2)	434	(1)	54	(15)	241	(10)	152	(3)	675	(2)
Undetermined[4]	196	(4)	845	(3)	43	(12)	236	(10)	239	(4)	1081	(3)
SUBTOTAL [% of all cases]	5041	[93]	31708	[93]	365	[7]	2321	[7]	5406	[100]	34029	[100]
CHILDREN[5]												
Hemophilia/Coagulation Disorder	2	(5)	23	(9)			2	(1)	2	(3)	25	(5)
Parent with/at risk of AIDS[6]	30	(73)	195	(73)	28	(82)	186	(86)	58	(77)	381	(79)
Transfusion, Blood/Components	5	(12)	37	(14)	2	(6)	20	(9)	7	(9)	57	(12)
Undetermined[4]	4	(10)	12	(4)	4	(12)	9	(4)	8	(11)	21	(4)
SUBTOTAL [% of all cases]	41	[55]	267	[55]	34	[45]	217	[45]	75	[100]	484	[100]
TOTAL [% of all cases]	5082	[93]	31975	[93]	399	[7]	2538	[7]	5481	[100]	34513	[100]

B. TRANSMISSION CATEGORIES BY RACIAL/ETHNIC GROUP

	WHITE, NOT HISPANIC		BLACK, NOT HISPANIC		HISPANIC		OTHER[7]/ UNKNOWN		TOTAL	
	Cumulative		Cumulative		Cumulative		Cumulative		Cumulative	
ADULTS/ADOLESCENTS	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)
Homosexual/Bisexual Male	16620	(80)	3270	(40)	2286	(48)	235	(71)	22411	(66)
Intravenous (IV) Drug Abuser	1063	(5)	2860	(35)	1688	(36)	35	(11)	5646	(17)
Homosexual Male and IV Drug Abuser	1700	(8)	568	(7)	324	(7)	15	(5)	2607	(8)
Hemophilia/Coagulation Disorder	260	(1)	15	(0)	20	(0)	5	(2)	300	(1)
Heterosexual Cases[3]	175	(1)	959	(12)	170	(4)	5	(2)	1309	(4)
Transfusion, Blood/Components	522	(3)	96	(1)	42	(1)	15	(5)	675	(2)
Undetermined[4]	398	(2)	456	(6)	205	(4)	22	(7)	1081	(3)
SUBTOTAL [% of all cases]	20738	[61]	8224	[24]	4735	[14]	332	[1]	34029	[100]
CHILDREN[5]										
Hemophilia/Coagulation Disorder	16	(16)	5	(2)	3	(3)	1	(33)	25	(5)
Parent with/at risk of AIDS[6]	44	(45)	238	(88)	97	(85)	2	(67)	381	(79)
Transfusion, Blood/Components	32	(33)	15	(6)	10	(9)			57	(12)
Undetermined[4]	6	(6)	11	(4)	4	(4)			21	(4)
SUBTOTAL [% of all cases]	98	[20]	269	[56]	114	[24]	3	[1]	484	[100]
TOTAL [% of all cases]	20836	[60]	8493	[25]	4849	[14]	335	[1]	34513	[100]

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[1] These data are provisional.

[2] Cases with more than one risk factor other than the combinations listed in the tables or footnotes are tabulated only in the category listed first.

[3] Includes 663 persons (125 men, 538 women) who have had heterosexual contact with a person with AIDS or at risk for AIDS and 646 persons (518 men, 128 women) without other identified risks who were born in countries in which heterosexual transmission is believed to play a major role although precise means of transmission have not yet been fully defined.

Includes patients on whom risk information is incomplete (due to death, refusal to be interviewed or loss to follow-up), patients still under investigation, men reported only to have had heterosexual contact with a prostitute, and interviewed patients for whom no specific risk was identified.

[5] Includes all patients under 13 years of age at time of diagnosis.

[6] Epidemiologic data suggest transmission from an infected mother to her fetus or infant during the perinatal period.

[7] Includes patients whose race/ethnicity is Asian/Pacific Islander (204 persons) and American Indian/Alaskan Native

C. AIDS CASES BY STATE OF RESIDENCE AND DATE OF REPORT TO CDC

STATE OF RESIDENCE	Year Ending APR 20, 1986		Year Ending APR 20, 1987		CUMULATIVE TOTAL SINCE JUNE 1981					
					Adult/Adolescent		Children		Total	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
New York	2945	(29.3)	3776	(25.6)	10164	(29.9)	178	(36.8)	10342	(30.0)
California	2342	(23.3)	3308	(22.4)	7833	(23.0)	28	(5.8)	7861	(22.8)
Florida	664	(6.6)	1063	(7.2)	2277	(6.7)	60	(12.4)	2337	(6.8)
xas	608	(6.0)	1034	(7.0)	2130	(6.3)	12	(2.5)	2142	(6.2)
w Jersey	598	(5.9)	877	(5.9)	1997	(5.9)	66	(13.6)	2063	(6.0)
Illinois	257	(2.6)	410	(2.8)	856	(2.5)	10	(2.1)	866	(2.5)
Pennsylvania	226	(2.2)	323	(2.2)	744	(2.2)	9	(1.9)	753	(2.2)
Georgia	213	(2.1)	365	(2.5)	705	(2.1)	11	(2.3)	716	(2.1)
Massachusetts	224	(2.2)	314	(2.1)	696	(2.0)	12	(2.5)	708	(2.1)
District of Columbia	216	(2.1)	273	(1.8)	626	(1.8)	8	(1.7)	634	(1.8)
Maryland	156	(1.6)	248	(1.7)	518	(1.5)	8	(1.7)	526	(1.5)
Washington	117	(1.2)	208	(1.4)	425	(1.2)	1	(0.2)	426	(1.2)
Louisiana	120	(1.2)	199	(1.3)	411	(1.2)	6	(1.2)	417	(1.2)
Connecticut	110	(1.1)	186	(1.3)	388	(1.1)	14	(2.9)	402	(1.2)
Virginia	146	(1.5)	169	(1.1)	392	(1.2)	6	(1.2)	398	(1.2)
Colorado	88	(0.9)	196	(1.3)	358	(1.1)	2	(0.4)	360	(1.0)
Ohio	57	(0.6)	228	(1.5)	349	(1.0)	2	(0.4)	351	(1.0)
Puerto Rico	102	(1.0)	107	(0.7)	310	(0.9)	18	(3.7)	328	(1.0)
Michigan	84	(0.8)	142	(1.0)	290	(0.9)	3	(0.6)	293	(0.8)
Missouri	59	(0.6)	120	(0.8)	220	(0.6)	1	(0.2)	221	(0.6)
North Carolina	75	(0.7)	96	(0.6)	208	(0.6)	2	(0.4)	210	(0.6)
Minnesota	71	(0.7)	94	(0.6)	186	(0.5)			186	(0.5)
Arizona	61	(0.6)	79	(0.5)	180	(0.5)	1	(0.2)	181	(0.5)
Indiana	46	(0.5)	74	(0.5)	152	(0.4)	2	(0.4)	154	(0.4)
gon	43	(0.4)	81	(0.5)	154	(0.5)			154	(0.4)
South Carolina	49	(0.5)	59	(0.4)	124	(0.4)	5	(1.0)	129	(0.4)
Hawaii	25	(0.2)	69	(0.5)	125	(0.4)	1	(0.2)	126	(0.4)
Wisconsin	16	(0.2)	70	(0.5)	111	(0.3)			111	(0.3)
Alabama	28	(0.3)	61	(0.4)	103	(0.3)	5	(1.0)	108	(0.3)
Oklahoma	33	(0.3)	56	(0.4)	104	(0.3)	1	(0.2)	105	(0.3)
Tennessee	32	(0.3)	63	(0.4)	102	(0.3)	1	(0.2)	103	(0.3)
Nevada	21	(0.2)	49	(0.3)	84	(0.2)			84	(0.2)
Kentucky	20	(0.2)	38	(0.3)	79	(0.2)			79	(0.2)
Rhode Island	13	(0.1)	43	(0.3)	69	(0.2)			69	(0.2)
Kansas	16	(0.2)	43	(0.3)	67	(0.2)	1	(0.2)	68	(0.2)
Utah	23	(0.2)	24	(0.2)	56	(0.2)	3	(0.6)	59	(0.2)
New Mexico	17	(0.2)	31	(0.2)	55	(0.2)			55	(0.2)
Arkansas	18	(0.2)	31	(0.2)	53	(0.2)			53	(0.2)
Delaware	14	(0.1)	22	(0.1)	48	(0.1)			48	(0.1)
Mississippi	11	(0.1)	31	(0.2)	47	(0.1)			47	(0.1)
Maine	16	(0.2)	22	(0.1)	41	(0.1)	1	(0.2)	42	(0.1)
Iowa	17	(0.2)	17	(0.1)	40	(0.1)	1	(0.2)	41	(0.1)
Nebraska	10	(0.1)	14	(0.1)	27	(0.1)			27	(0.1)
New Hampshire	8	(0.1)	14	(0.1)	25	(0.1)	2	(0.4)	27	(0.1)
Alaska	11	(0.1)	9	(0.1)	25	(0.1)			25	(0.1)
West Virginia	7	(0.1)	9	(0.1)	21	(0.1)	2	(0.4)	23	(0.1)
Vermont	4	(0.0)	7	(0.0)	13	(0.0)			13	(0.0)
Idaho	4	(0.0)	5	(0.0)	8	(0.0)	1	(0.2)	9	(0.0)
Montana	2	(0.0)	6	(0.0)	8	(0.0)			8	(0.0)
in Islands	1	(0.0)	3	(0.0)	7	(0.0)			7	(0.0)
Wyoming	2	(0.0)	4	(0.0)	7	(0.0)			7	(0.0)
North Dakota	3	(0.0)	2	(0.0)	5	(0.0)			5	(0.0)
South Dakota	2	(0.0)	2	(0.0)	4	(0.0)			4	(0.0)
Guam	1	(0.0)			1	(0.0)			1	(0.0)
Trust Territory					1	(0.0)			1	(0.0)
TOTAL	10052	(100.0)	14774	(100.0)	34029	(100.0)	484	(100.0)	34513	(100.0)

D. AIDS CASES BY TRANSMISSION CATEGORIES AND DATE OF REPORT TO CDC, TWELVE-MONTH TOTALS

TRANSMISSION CATEGORIES[1]	Year Ending APR 20, 1986		Year Ending APR 20, 1987		CUMULATIVE CASES AND DEATHS SINCE JUNE 1981			
ADULTS/ADOLESCENTS	Number	(%)	Number	(%)	Number	(%)	Deaths	(% Cases)
Homosexual/Bisexual Male	6606	(66.8)	9615	(66.0)	22411	(65.9)	12626	(64.3)
Intravenous (IV) Drug Abuser	1702	(17.2)	2291	(15.7)	5646	(16.6)	3414	(17.4)
Homosexual Male and IV Drug Abuser	671	(6.8)	1036	(7.1)	2607	(7.7)	1553	(7.9)
Hemophilia/Coagulation Disorder	93	(0.9)	141	(1.0)	300	(0.9)	174	(0.9)
Heterosexual Cases[2]	338	(3.4)	573	(3.9)	1309	(3.8)	745	(3.8)
Transfusion, Blood/Components	190	(1.9)	365	(2.5)	675	(2.0)	463	(2.4)
Undetermined[3]	287	(2.9)	547	(3.8)	1081	(3.2)	655	(3.3)
SUBTOTAL	9887	(100.0)	14568	(100.0)	34029	(100.0)	19630	(100.0)
CHILDREN[4]								
Hemophilia/Coagulation Disorder	8	(4.8)	12	(5.8)	25	(5.2)	13	(4.2)
Parent with/at risk of AIDS[5]	129	(78.2)	165	(80.1)	381	(78.7)	238	(77.3)
Transfusion, Blood/Components	25	(15.2)	17	(8.3)	57	(11.8)	44	(14.3)
Undetermined[3]	3	(1.8)	12	(5.8)	21	(4.3)	13	(4.2)
SUBTOTAL	165	(100.0)	206	(100.0)	484	(100.0)	308	(100.0)
TOTAL	10052		14774		34513		19938	

E. AIDS CASES BY DATE OF DIAGNOSIS AND STANDARD METROPOLITAN STATISTICAL AREA (SMSA) OF RESIDENCE[6]

SMSA OF RESIDENCE	POPULATION[7]	BEFORE 1984	1984	1985	1986	1987[8]	CUMULATIVE TOTAL
New York, NY	9.12	1567	1694	2550	3160	422	9393
San Francisco, CA	3.25	450	601	919	1230	203	3403
Los Angeles, CA	7.48	351	439	831	1147	233	3001
Houston, TX	2.91	103	174	323	448	30	1078
Miami, FL	1.63	178	192	276	333	50	1029
Washington, DC	3.06	78	137	322	366	96	999
Newark, NJ	1.97	125	137	228	281	60	831
Chicago, IL	7.10	69	121	219	311	48	768
Dallas, TX	2.97	34	84	168	287	43	616
Philadelphia, PA	4.72	56	108	185	245	16	610
Atlanta, GA	2.03	41	70	161	233	57	562
Boston, MA	2.76	59	75	144	197	47	522
Nassau-Suffolk, NY	2.61	56	67	112	164	21	420
Ft Lauderdale, FL	1.02	36	60	122	171	25	414
San Diego, CA	1.86	31	43	113	190	33	410
Jersey City, NJ	0.56	53	57	119	131	33	393
Seattle, WA	1.61	11	52	97	137	40	337
New Orleans	1.19	19	50	85	122	27	303
REST OF U.S.	172.28	809	1424	2697	3797	697	9424
TOTAL	230.11	4126	5585	9671	12950	2181	34513

[1] Cases with more than one risk factor other than the combinations listed in the tables or footnotes are tabulated only in the category listed first.

[2] Includes 663 persons (125 men, 538 women) who have had heterosexual contact with a person with AIDS or at risk for AIDS and 646 persons (518 men, 128 women) without other identified risks who were born in countries in which heterosexual transmission is believed to play a major role although precise means of transmission have not yet been fully defined.

[3] Includes patients on whom risk information is incomplete (due to death, refusal to be interviewed or loss to follow-up), patients still under investigation, men reported only to have had heterosexual contact with a prostitute, and interviewed patients for whom no specific risk was identified.

[4] Includes all patients under 13 years of age at time of diagnosis.

[5] Epidemiologic data suggest transmission from an infected mother to her fetus or infant during the perinatal period.

[6] This table cumulates cases by DATE OF DIAGNOSIS rather than DATE OF REPORT. Because of this difference, totals may differ from those in other tables and will change with late reports and new data or information. These data are provisional. Data are reported only for SMSA's with greater than 300 reported cases of AIDS.

[7] Population of SMSA's in millions as reported in the 1980 CENSUS.

F. AIDS CASES BY RISK FACTOR COMBINATIONS (ADULTS/ADOLESCENTS)[1]

	Number	Percent
AIDS CASES REPORTED TO HAVE A SINGLE RISK FACTOR		
Homosexual/Bisexual Male	21807	(64.1)
Intravenous (IV) Drug Abuse	5086	(14.9)
Hemophilia/Coagulation Disorder	174	(0.5)
Heterosexual Contact[2]	1246	(3.7)
Transfusion, Blood/Components	675	(2.0)
Undetermined[3]	1081	(3.2)
SUBTOTAL	30069	(88.4)
AIDS CASES REPORTED TO HAVE MULTIPLE RISK FACTORS		
Homosexual-Bi Male/Blood Transfusion	405	(1.2)
Homosexual-Bi Male/Heterosexual Contact	185	(0.5)
Homosexual-Bi Male/Heterosexual Contact/Blood Transfusion	6	(0.0)
Homosexual-Bi Male/Hemophilia	4	(0.0)
Homosexual-Bi Male/Hemophilia/Blood Transfusion	4	(0.0)
Homosexual-Bi Male/IV Drug Abuse	2449	(7.2)
Homosexual-Bi Male/IV Drug Abuse/Blood Transfusion	86	(0.3)
Homosexual-Bi Male/IV Drug Abuse/Heterosexual Contact	62	(0.2)
Homosexual-Bi Male/IV Drug Abuse/Heterosexual Contact/Blood Transfusion	5	(0.0)
Homosexual-Bi Male/IV Drug Abuse/Hemophilia	2	(0.0)
Homosexual-Bi Male/IV Drug Abuse/Hemophilia/Blood Transfusion	3	(0.0)
IV Drug Abuse/Blood Transfusion	171	(0.5)
IV Drug Abuse/Heterosexual Contact	367	(1.1)
IV Drug Abuse/Heterosexual Contact/Blood Transfusion	17	(0.0)
IV Drug Abuse/Hemophilia	1	(0.0)
IV Drug Abuse/Hemophilia/Blood Transfusion	4	(0.0)
Hemophilia/Blood Transfusion	124	(0.4)
Hemophilia/Heterosexual Contact	1	(0.0)
Hemophilia/Heterosexual Contact/Blood Transfusion	1	(0.0)
Heterosexual Contact/Blood Transfusion	63	(0.2)
SUBTOTAL	3960	(11.6)
TOTAL	34029	(100.0)

[1] These data are provisional. Not all risk factors may have been determined or reported for all cases.

[2] Includes persons who have had heterosexual contact with a person with AIDS or at risk for AIDS and persons without other identified risks who were born in countries in which heterosexual transmission is believed to play a major role although precise means of transmission have not yet been fully defined.

[3] Includes patients on whom risk information is incomplete (due to death, refusal to be interviewed or loss to follow-up), patients still under investigation, men reported only to have had heterosexual contact with a prostitute, and interviewed patients for whom no specific risk was identified.

G. CASES OF AIDS AND CASE-FATALITY RATES BY HALF-YEAR OF DIAGNOSIS, UNITED STATES

		NUMBER OF CASES	NUMBER OF KNOWN DEATHS[1]	CASE-FATALITY RATE
1981	Jan-June	85	78	92%
	July-Dec	179	160	89%
1982	Jan-June	364	319	88%
	July-Dec	639	555	87%
1983	Jan-June	1206	1049	87%
	July-Dec	1579	1321	84%
1984	Jan-June	2415	1923	80%
	July-Dec	3170	2484	78%
1985	Jan-June	4321	3114	72%
	July-Dec	5350	3409	64%
1986	Jan-June	6314	3110	49%
	July-Dec	6636	1978	30%
1987	Jan-Apr 20	2181	376	17%
TOTAL[2]		34513	19938	58%

H. REPORTED CASES AND DEATHS BY OPPORTUNISTIC DISEASE CATEGORY

	CASES REPORTED SINCE JANUARY 1/DEATHS				CUMULATIVE CASES/DEATHS			
	Reported Cases		Known Deaths[4]		Reported Cases		Known Deaths	
DISEASE CATEGORY REPORTED[3]	Number	(% Total)	Number	(% Cases)	Number	(% Total)	Number	(% Cases)
Pneumocystis carinii Pneumonia	3623	(66)	971	(27)	22332	(65)	13058	(58)
Other Opportunistic Diseases	1300	(24)	457	(35)	7711	(22)	4819	(62)
Kaposi's Sarcoma	558	(10)	85	(15)	4470	(13)	2061	(46)
TOTAL	5481	(100)	1513	(28)	34513	(100)	19938	(58)

I. AGE AT DIAGNOSIS BY RACIAL/ETHNIC GROUP

	WHITE, NOT HISPANIC		BLACK, NOT HISPANIC		HISPANIC		OTHER[5]/ UNKNOWN		TOTAL	
	Cumulative		Cumulative		Cumulative		Cumulative		Cumulative	
AGE GROUP	Number	(%)	Number	(%)	Number	(%)	Number	(%)	Number	(%)
Under 5	74	(0)	247	(3)	105	(2)	2	(1)	428	(1)
5 - 12	24	(0)	22	(0)	9	(0)	1	(0)	56	(0)
13 - 19	57	(0)	54	(1)	27	(1)	3	(1)	141	(0)
20 - 29	3959	(19)	2128	(25)	1099	(23)	63	(19)	7249	(21)
30 - 39	9640	(46)	4027	(47)	2286	(47)	155	(46)	16108	(47)
40 - 49	4717	(23)	1411	(17)	938	(19)	82	(24)	7148	(21)
Over 49	2365	(11)	604	(7)	385	(8)	29	(9)	3383	(10)
TOTAL [% OF ALL CASES]	20836	[60]	8493	[25]	4849	[14]	335	[1]	34513	[100]

[1] Reporting of deaths is incomplete.

[2] Table totals include 74 cases diagnosed prior to 1981. Of these 74 cases, 62 are known to have died.

[3] Disease categories are ordered hierarchically. Cases with more than one disease are tabulated only in the disease category listed first. Kaposi's sarcoma has been reported in 880 cases since January 1 and in 7163 cases cumulatively.

[4] Deaths are only in cases reported to CDC since January 1 of current year.

[5] Includes patients whose race/ethnicity is Asian/Pacific Islander (204 persons) and American Indian/Alaskan Native (34 persons).

Mr. WAXMAN. Thank you very much, Dr. Lane.
Dr. Krim.

STATEMENT OF MATHILDE KRIM

Ms. KRIM. Mr. Chairman, Congressman Leland.

What is frightening about AIDS is the deadly nature of the disease of the disease, the fact that it is transmissible, that it is spreading now, including in the heterosexual community, in fact where it spreads now at a faster rate than among the previously identified high-risk groups, and that there is no end in sight to the epidemic.

To me, in addition, what is frightening is the quality of information the public has about this situation, which is appalling. And this applies to every type of public.

AIDS, the public should understand, is a result of a slow, progressive and relentless deterioration of the natural immune defense system caused by a viral infection. The virus that causes AIDS is called the Human Immune Deficiency Virus, or HIV. The HIV does not kill directly. What kills is a variety of other infections and cancers to which HIV infected persons progressively lose their resistance and that medicine cannot treat effectively.

The HIV infection is for life, once acquired. The human body does not develop resistance to HIV. The HIV is treacherous because it does not cause symptoms immediately. There is a very long incubation period, one that can last many years between infection and the occurrence of clinical symptoms.

Since HIV is mainly transmitted sexually in the natural course of things, it is transmitted usually between people who appear healthy and are usually unsuspecting of having been at risk or having become infected. People who transmit HIV can be gay or straight, can be young or old, and can be of any race.

In New York, we are suffering a grievous epidemic of HIV infection and AIDS. In Houston, that is already the fourth city in the Nation in this epidemic, as was pointed out earlier, can expect to experience what New York City is experiencing now, unless it acts locally, rapidly and energetically.

The HIV was introduced probably in New York among the gay community in the early or midseventies. Because it did not cause disease and nobody was aware of this virus, or AIDS to come several years later, nothing was done about the spreading infection, of course. And by 1981, when the first cases of AIDS occurred, we had already 30 to 50 percent of individuals in the gay community who were infected.

In 1983, we knew that AIDS was not a gay disease and we did not act on this information. In 1984, we knew the existence of the causative virus, and we still did not act effectively by warning the people at risk. We forgot that the so-called high-risk groups included also bisexuals and drug abusers. And these transmitted the infection into the larger heterosexual population.

Now, in 1987, 40 percent of all cases of AIDS in New York occur among heterosexuals. Ten percent of the cases occur among women. AIDS is the greatest killer of all women between the ages of 25 and 29 years of age in New York. And we have hundreds of sick children.

Dr. Joseph, our Commissioner of Health, expect the birth of over 800 babies with HIV infection in 1987 alone, and he has stated that we have half a million people infected with HIV virus.

The screening of military recruits done by the Army has revealed that in the general population in Manhattan, between the ages of 17 and 25, 1 in 100 is infected. And, if minority group people are selected out among Army recruits, the rate of infection is 1 in 50.

Minorities, as we heard already, are much over-represented among all groups affected by HIV infection or AIDS. Nearly 50 percent of all cases of AIDS in New York occur among minorities. Seventy-five percent of all women with AIDS are minority group women. And 90 percent of all children with AIDS are minority group children.

And what is the fate of HIV-infected people? We used to believe that only 10 or 20 or 30 percent of them would develop disease. We now know over the last few months, we have learned that after 6 years, over 50 percent of HIV-infected people develop serious clinical symptoms. And because the rates at which infected people become sick each year has remained stable has not decreased yet it is quite possible that, after 10 or 15 years, 100 percent of all people will become sick.

There is a silver lining in the AIDS clouds. And this is that there is no casual transmission and that research will certainly be able to do something and bring control of the epidemic with treatment or a vaccine within 5 to 10 years. There is a race going on between research and virus spread at this time, and we are at a very important crossroads.

We have a collective the collective means we have are economic resources and solid information on how the AIDS virus spreads. Individually, we have the capacity to understand this information if it is made available, and we have the capability to exercise self-control over our own sexual behavior.

The job of educating and changing people's ways can be done, as we have learned, from the self-help organizations in the gay community that have demonstrated that it can be done. There are no countless people in institutions that stand ready to undertake the enormous educational and counseling job that must be done. They must be given the resources to do it. We do have a chance in this country to slow and perhaps even halt the spread of AIDS through education, first, and through the fruits of research later. Our children will justly hold us accountable and will not forgive us if we do not do the job. Thank you.

Mr. WAXMAN. Thank you very much, Dr. Krim.

Dr. Haughton.

STATEMENT OF JAMES G. HAUGHTON

Mr. HAUGHTON. Thank you for the opportunity to address you today. I think you will find that my perspective on the problem is slightly different than my colleagues.

The AIDS is a serious problem. It is not the only health problem in Houston: and, therefore, as director of Public Health of this city, it has been my responsibility to help keep some perspective on the problem.

The 1,135 cases in the Houston AIDS registry include all reported cases diagnosed from January 1 of 1980 through April 6 of this year among residents of the Houston Standard Metropolitan Statistical Area. That area includes all of Harris County, Montgomery County, Fort Bend, Brazoria, Liberty and Waller Counties. Although cases have been reported from each of these counties, Harris County residents account for 95 percent of the total, and Houston residents account for 85 percent of the total of the SMSA cases.

Comparisons of the current national statistics on AIDS with those for Houston reveal some interesting differences. And I have provided you with a chart there that shows those differences. Transmission categories, in both cases, in both case series are assigned according to a nationally standardized system in which, when there is a case with multiple characteristics, the case is only counted in one of the transmission categories.

Now, nationally, the largest transmission category is "Homosexual and Bisexual Males," which represents 64.2 percent of cases throughout the United States, but 83 percent in Houston. Nationally, the "Intravenous Drug User" category is second largest transmission category accounting for 17 percent. In Houston, it is 1.7 percent. Houston's second largest transmission category is "Homosexual and Bisexual Male and IV Drug User," which is a recently instituted category by CDC and is intended to reflect more accurate the risk status of cases who were previously classified only as homosexual or bisexual male. That group represents 10 percent of all Houston cases and 7½ percent nationwide.

The picture that emerges from these comparisons is one in which IV drug use plays a much larger role in the transmission of AIDS nationwide than it does in Houston. Upon examination of regional statistics, however, it becomes apparent that IV drug use as a solitary factor is geographically specific. Approximately 75 percent of all U.S. AIDS cases attributed to IV drug use come from the States of New York and New Jersey. If New York and New Jersey cases are excluded, the percentage of all other U.S. AIDS cases attributable to IV drug use drops from 17 percent to 4.1 percent. Therefore, 4.1 percent seems to be a more accurate description of the contribution of IV drug use to AIDS in areas of the country other than New York and New Jersey. Even after this adjustment, the Houston value of 1.7 percent is still substantially less than this amended National average.

A notable characteristic of the Houston registry is the absence of confirmed cases attributable to hemophilia where there are 313 cases in the national registry and none in the City of Houston.

Houston cases also differ from the U.S. cases with respect to several demographic characteristics. The Houston cases tend to be younger, and to consist of a larger percentage of whites and males than the National cases. Both have a high percentage of cases concentrated in the 30–49 age range: but in Houston 79 percent are under 40, while nationally, it is 69 percent that are under 40. In the U.S. registry, 60 percent of cases are white, 25 percent are Black, and 14 percent are Hispanics and 1 percent are categorized as "Other" or "Unknown." This leads to the conclusion that Blacks and Hispanics are over-represented among AIDS cases in the United States.

In the Houston registry, by comparison, 79 percent of cases are white, 11 percent are Black, 10 percent are Hispanics and less than 1 percent are characterized as "Other," while in the general population of Houston, 50 percent of the population is white, 27 percent are Black and 20 percent are Hispanics. Minorities are therefore under-represented among AIDS cases in Houston. In Houston, 98 percent of the cases are males, compared to 93 percent nationally.

Although the CDC no longer requests the investigation of transfusion-associated cases, we still have guidelines from the Texas Department of Health. And we still identify those cases. Since the Houston AIDS surveillance began, 29 transmission-associated cases have been investigated by our Bureau of Epidemiology. All of those cases had their beginning prior to the use of the HIV antibody test.

There are only eight pediatric cases confirmed in the City of Houston, four of which are white, three are Black and one is Hispanic. This is in contrast to the U. S. pediatric cases where the majority of the pediatric cases, more than 50 percent are Black. Five of our pediatric cases acquired their infection from the parents who were at risk of AIDS.

There are other areas of controversy within the subject of AIDS, but I have covered them quite thoroughly in the paper I have presented to you and will not take the time to repeat them now. Thank you.

[Testimony resumes on p. 120.]

[The statement of Mr. Haughton follows:]

STATEMENT OF JAMES G. HAUGHTON

AIDS IN HOUSTON, April 1987

Acquired Immune Deficiency Syndrome (AIDS) was recognized as a new disease entity in Los Angeles and New York City in the summer of 1981. Recognition of the disease, as well as the disease itself, is now widespread. In the United States, additional cases first appeared in other large metropolitan areas, but now every state has reported AIDS cases to the Centers for Disease Control (CDC).

Although Houston was not among the first group of cities to recognize a cluster of cases in 1981, Houston currently has the fourth largest number of confirmed cases. Given the current number of cases reported (April 6, 1987) by New York City (9,382), San Francisco (3,309), and Los Angeles (2,917), Houston is a distant fourth in this ranking with 1,135 cases. This, however, is still an onerous distinction.

The 1,135 cases in the Houston AIDS registry include all reported cases diagnosed from January 1, 1980 through April 6, 1987 among residents of the Houston Standard Metropolitan Statistical Area (SMSA). The Houston SMSA is comprised of the city of Houston, the remaining areas of Harris County and Montgomery, Fort Bend, Brazoria, Liberty, and Waller counties. Although cases have been reported from each county in the SMSA, Harris County residents account for 95% of the total. Houston residents, account for 85% of all the SMSA cases.

Comparisons of the current national statistics on AIDS (April 6, 1987) with those for Houston reveal some interesting differences. Transmission categories in both case series are assigned according to a nationally standardized system, which lists risk factors hierarchically. Cases having multiple characteristics are counted only in the transmission category with greater importance as indicated by its position in the hierarchy. (See Table 1.) Nationally, the largest transmission category is "Homosexual/Bisexual Male", which represents 64.2% of other U.S. cases and 83.1% of Houston cases. Nationally, the "Intravenous (IV) Drug User" category is the second largest transmission category accounting for 17.0% of cases. However, only 1.7% of all Houston cases fall into this category, making it the third largest category in Houston. Houston's second largest transmission category is "Homosexual/Bisexual Male and IV Drug User". The CDC only recently instituted this category. It is intended to reflect more accurately the risk status of cases who were previously classified in the homosexual/bisexual transmission group, but who also use IV drugs. They represent 10.0% of all Houston cases and 7.5% of cases elsewhere.

The picture that emerges from these comparisons is one in which IV drug use plays a much larger role in the transmission of AIDS nationwide than it does in Houston. Upon examination of regional statistics, however, it becomes apparent that IV drug use as a solitary factor is geographically specific. Approximately 75% of all U.S. AIDS cases attributed to IV drug use come from the states of New York and New Jersey. If New York and New Jersey cases are excluded, the percentage of all other U.S. AIDS cases attributable to IV drug use drops from 17.0% to 4.1%. Therefore, 4.1% seems to be a more accurate description of the contribution of IV drug use to AIDS in areas of the country other than New York or New Jersey. Even after this adjustment the Houston value of 1.7% is still substantially less than this amended national average.

A limited number of local cases have been classified in the transmission categories "Heterosexual Cases", "Transfusion Recipient", and "Parent at Risk for AIDS". Each of these risk groups constitute a smaller percentage of the

Houston cases than they do nationally. A notable characteristic of the Houston registry is the absence of confirmed cases attributable to hemophilia while there are 313 cases (1%) in the national registry. Although the Bureau of Epidemiology has received several reports of suspect cases among hemophiliacs, none of these have met the CDC case definition.

The percentage of cases without an apparent risk factor is often seized upon by those who want to argue that we do not know all the means of transmission. Houston's experience is similar to the national with 3.2% among other U.S. cases and 2.5% (29 cases) among Houston cases. Of the 29 Houston cases, twelve have been interviewed and found to have no established risk factors, nine died before interview, three refused a detailed interview, one was lost to follow-up, and four are currently under investigation. Of the 12 cases interviewed, three cases indicated contact with prostitutes as their only probable risk factor.

Houston AIDS cases also differ from other U.S. cases with respect to several demographic characteristics. The Houston cases tend to be younger, and to consist of a larger percentage of Whites and males than the national cases. Both have a high percentage of cases concentrated in the 30-49 age range, but in Houston 79% are under 40, while nationally only 69% are under 40. In the U.S. registry, 60% of cases are White, 25% Black, 14% Hispanic, and 1% Other/Unknown. This leads to the conclusion that Blacks and Hispanics are over-represented among AIDS cases in the U.S. In the Houston registry by comparison, 79% of cases are White, 11% are Black, 10% are Hispanic and less than 1% are categorized as Others while in the general population of Houston 50% are White, 27% are Black and 20% are Hispanic. Minorities are therefore under-represented among AIDS cases in Houston. In Houston, 98% of the cases are males, compared to 93% nationally.

The distribution of the major disease groups among Houston cases and national cases differs only slightly. Pneumocystis carinii pneumonia (PCP) is the disease most frequently associated with AIDS in both. It affects 61% of Houston cases and 65% of U.S. cases. Kaposi's sarcoma occurs in 28% of the Houston cases and 21% of the national cases.

Although the CDC no longer requests the investigation of transfusion-associated (TA) AIDS cases, the Texas Department of Health has guidelines for identifying the donors at risk for AIDS in such cases. Since the Houston AIDS surveillance began, 29 TA cases have been investigated by the Bureau of Epidemiology. Of the 15 TA cases among residents of the Houston SMSA, eight have been directly linked to a HIV antibody positive donor, a donor who is now an AIDS or ARC patient, and/or a donor in a risk group for AIDS. All of the TA cases received their blood products prior to the implementation of stringent screening procedures for AIDS antibody which have been in effect at all U.S. blood banks since late Spring, 1985.

The Houston area has 28 confirmed AIDS cases among females. Twenty-three cases are among adults and five are among children. The average age of adult female cases is 37 years. The largest transmission category for adult females in Houston is heterosexual contact, with 9 cases reported. This is not the case nationally where most are attributed to IV drug use. In Houston, five adult female cases are attributed to IV drug use. All five are Black. There are five adult female cases linked to blood transfusions. Four are White females and one is an Hispanic female; all received blood products prior to current screening for HIV antibodies now done by all blood centers. The remaining four adult cases are classified as "Unknown Risk Factor". One female case reported a history involving 15 sexual partners in her lifetime. Another estimated over 300 partners in her lifetime. In all four cases, no male sexual partner was known to the female case as being at risk for AIDS.

As of April 6, 1987, there are only eight pediatric cases confirmed with onset of symptoms in Houston. Four (50%) are White, three (38%) are Black and one (13%) is Hispanic. This is in contrast to the U.S. pediatric cases, where the majority of the pediatric cases (56%) are Black. There are three males and five females. Five of the pediatric cases acquired their infections from their parents who were at risk for AIDS. The remaining three cases acquired their infection from transfusions before the spring of 1985. Houston's low number of pediatric cases may be related to the low number of cases attributed to IV drug use, especially among women.

Accuracy of the Data in the AIDS Registry

Despite the fact that 1,135 confirmed cases of AIDS with a 65% mortality rate clearly indicates a serious public health problem in Houston, there is a constant concern as to whether or not the AIDS registry accurately describes the disease in this community; describes it in terms of the number of persons affected, as well as the population groups at greatest risk. To understand the accuracy of the descriptive data available from the Houston AIDS registry and its utility for policy making and planning, it is necessary to understand how reporting of all communicable diseases and of AIDS, in particular, actually works.

The degree to which any disease is reported to health authorities depends on a multitude of factors. Perhaps the most important is whether or not the disease is required to be reported by state health regulations. Without such a requirement, physicians and hospitals will be very reluctant to provide detailed information without the patient's consent for fear of violating patient confidentiality. If there is a large, obvious outbreak where detailed patient information is needed to minimize the spread of disease, the broad powers of the local or state health authority can be invoked to overcome this reluctance. This also provides legal protection for physicians who do release germane patient information to health authorities during a short term emergency.

Once a disease is added to the list of reportable diseases, there are several practical considerations that will determine the degree to which cases will actually be reported. A key factor that encourages reporting is a genuine feeling among those required to report that reporting each and every case will help local health officials limit subsequent spread of the disease. Other considerations that encourage reporting include requiring only an extremely limited number of data items, so the time and effort required to report a case is minimal; and not requiring information about sexual practices and drug use. Reporting is also less difficult if the risk factors associated with acquiring the disease are not associated with any social stigmas.

Although AIDS is a reportable disease in Texas it is easy to understand why some might conclude that AIDS is a poorly reported disease. First, few physicians believe that reporting any or all of their cases will help stop the spread of AIDS, because there is neither a vaccine for unexposed persons nor a preventive treatment for contacts already exposed to a case. Second, the information required to mesh a diagnosis of AIDS with the CDC definition can be rather detailed. Finally, personal information regarding sexual preference and drug use is required to complete each case report, and the most commonly reported risk behaviors are associated with significant social stigmas.

Despite all this, AIDS is probably the most thoroughly reported communicable disease in Houston and in the U.S. The most important, but unfortunate, factor for thorough reporting is the very predictable course of the disease that eventually results in each case being hospitalized, at least once. Therefore, if a physician does not report cases among their clinic patients who are in the early stages of the disease, the case will be reported when that patient is admitted to the hospital. This delays the reporting of some cases, but they will eventually be reported.

Our documentation regarding the completeness of hospital reporting of confirmed AIDS cases in Houston is formidable. On a monthly basis, all death certificates filed with the Bureau of Vital Statistics are reviewed for deaths due to 18 different causes which may be related to AIDS. This process has identified an occasional case which had not previously been reported, but more importantly, has identified hospitals which had not been reporting cases. In an equivalent vein, the Bureau of Epidemiology also reviews the reporting performance of some 50 acute-care hospitals in the Houston area for five of the most commonly reported communicable diseases. Hospitals with significantly lower reporting rates of selected reportable diseases relative to comparably sized hospitals are identified as having a potential reporting problem. The infection control officers of these hospitals, and those of hospitals having discrepancies between case reports and death certificates, are contacted. They are informed of their responsibility to report as prescribed by state regulations, and of the need for accurate information about AIDS cases in order to monitor trends of transmission of the disease and to plan for care facilities of projected cases. In the one situation where this approach did not correct reporting problems, hospital officials were advised that steps could and would be initiated to have their Medicare certification revoked by the state for not being in compliance with all applicable state and local regulations. The problem was quickly rectified.

Additional documentation of nearly complete hospital-based reporting comes from two record validation studies. Two hospitals have undergone validation studies, one in 1985 and one in 1986, to assess surveillance. A third study at another hospital is currently in progress. In 1985, a validation study was done at one of the county hospitals. This hospital is a 467 bed general hospital which is part of the Harris County Hospital District. The hospital district provides indigent care. Printouts of 1984 patient discharge diagnoses suggestive of AIDS were reviewed. Eighty-five cases had codes suggestive of AIDS. Fourteen of these patients were found in our registry. Ten cases were reported by the hospital and four by other sources. The remaining cases were pared down to 28 patients for whom chart reviews were conducted to determine if any of these patients should be reported as AIDS cases. After reviewing these charts, one patient was identified and classified as a suspect/presumptive AIDS patient. This patient is an IV drug user with empirically treated (not confirmed) Candida esophagitis. Nonetheless, this was the only case who should have been reported by the hospital and was not.

A validation study was also conducted at a 700 bed hospital with a long history of underreporting communicable diseases. This history of underreporting was carefully documented for AIDS and several other reportable diseases over a 3 month period. The hospital administration was then presented with this documentation and was persuaded to assist with a record validation study. This validation study covered all reportable diseases since January 1986.

Pathology reports and medical record codes back to March 1983 were reviewed for illness associated with AIDS. Prior to this study, 7 of this hospital's cases had been identified from other sources, but were still incomplete for reporting purposes. These 7 were identified and completed due to the validation study. Ten new cases were reported after communication was reestablished with this hospital. Up to a year had elapsed from date of diagnosis to report for some of these cases. From the validation study itself, 6 cases were discovered that had never been reported. Therefore, at this time, a total of 23 AIDS cases have been completed and reported due to these negotiations with this hospital. For more than a year, this hospital has been an excellent reporting hospital.

In the process of this second record validation study, an often discussed reporting phenomenon, the duplication of cases in informal case counts, was documented. With the hospital in question, several physicians estimated that possibly 200 AIDS patients had been admitted since 1983 and few, if any, had been reported. In the final analysis, approximately 50 patients had been admitted, but, only six unreported cases were discovered by the validation study. The other cases had all been reported by other physicians and hospitals. Apparently, AIDS patients typically seek numerous clinical opinions. This results in a high level of reporting even if a limited number of care providers do not regularly report. This multiple opinion phenomenon is also the basic cause of highly exaggerated informal case counts. Each physician counts his or her cases without knowing which patients may have been seen by several other physicians. These other physicians also count these cases in their informal tallies.

Still, with all these indications of good or improved reporting compliance, without continuing encouragement and periodic feedback to those who report, compliance would deteriorate. To maintain regular contact a monthly AIDS Information Update was initiated and sent to all hospital reporting officers and physicians who have reported AIDS cases. The first issue was mailed January 1985 to approximately 50 persons. Currently, nearly 200 updates are mailed each month. The updates contain detailed statistical summaries of the Houston case registry, and an original narrative pointing out trends in the data or new developments in the CDC case definition. (See Attachment A.)

The preceding, however, applies only to the reporting of confirmed cases. Persons with symptoms consistent with AIDS, but who do not meet the CDC definition are not routinely reported even though they could be included under the state requirements for reporting. Persons who are HIV antibody positive but lacking significant symptoms, are not to be reported according to current policies of the Texas Department of Health.

This situation, which is typical of AIDS reporting in the U.S. in all but a few isolated locations, requires resource planners to make projections based on some multiple of the number of confirmed AIDS cases. Given the diligent efforts of the Bureau of Epidemiology in achieving a high level of reporting compliance, numerical projections based on the Houston AIDS case registry will not be compromised by the quality of the registry effort.

Rate of Increase

One of the more controversial aspects of AIDS involves the projections to estimate the number of future cases. Varying projections have been made. The Surgeon General's report contains an estimate of 270,000 cases of AIDS by the end of 1991 with 179,000 deaths. Other projections, if adhered to would soon project more U.S. cases than the country has population. One point of certain agreement is that the number of cases will continue to increase for the foreseeable future.

Although the official estimates published by the CDC are among the most realistic, they are probably overestimates. Quoting from the CDC paper published in the September-October 1986 issue of Public Health Reports, the author's concede that their models are "empirical in the sense that they reflect observed trends in the distribution of reported cases and assume these trends will continue unchanged over time." Although mathematical models can't sense change in the at risk population, public health officials and elected officials have to recognize changes as they begin to occur.

There are already strong indications that these projections are inaccurate. For example, CDC projected 34,090 to be diagnosed by the end of 1986. After allowing three full months (January through March, 1987) for receipt of delayed reports, 32,081 cases had actually been diagnosed through April 6, 1987. Only the case counts for 1986 were estimated in this projection; the remaining cases in this total were actual case counts. Therefore, when attention is focused on the actual projection of 15,800 to be diagnosed in 1986, it is found that the actual number reported for that year by April 6, 1987 is 12,732 or 20% less than expected. It is even below CDC's lower bound for 14,800 estimated cases. Given such an error in the first interval, with five additional intervals estimated, the 1991 estimate of 270,000 case needs to be revised downward.

There are two reasons why the model overestimated the cases. First is that the cases of AIDS being seen right now are primarily the result of activity which transpired two, four, or six years ago among homosexual males and IV drug users engaging with great frequency in practices that are very effective in transmitting the AIDS virus from one person to another. In short, these are persons who have lived in the "fast lane" of their respective lifestyles. Other homosexual males may not have been exposed to the virus because they limited their number of contacts, were very selective, or were extremely lucky. The second reason is that behavior did change as the seriousness of the situation began to be realized in 1984 and 1985. Many homosexual males became much more cautious. Certainly the warnings of AIDS spreading heterosexually have also had a dramatic chilling effect on the level of sexual activity among sexually active singles. These two factors may ultimately result in a significantly lower number of cases than the 270,000 projected for 1991.

In Houston, the trends of the disease over the past three years have been tracked. The first case was diagnosed retrospectively in the second half of 1980. Since the first half of 1982, the number of cases diagnosed has increased for each six-month interval to reach a high of 247 diagnosed in the first half of 1986. The totals for late 1986 and early 1987 are not yet complete, but both will probably exceed 250 cases each. (See Figure 1.)

Although the number of cases diagnosed during each half-year period will continue to increase for the foreseeable future, a slowing in the rate of increase of newly diagnosed cases has been noted. (See Table 2.) In 1983, the number of new cases diagnosed represented a 327% increase from 1982. For 1984, the percentage of increase was 126%. For 1985, it was 86%. For 1986 it was 45%.

With any luck, this trend, in terms of rate of increase, will continue and changes in personal behaviors which began occurring several years ago will speed this trend.

AIDS Antibody Screening

In Houston, HIV antibody testing is provided to the public in three settings. The Montrose Clinic Alternate Test Site provides free and anonymous testing. The Institute for Immunological Disorders offers testing for a fee of $30.00 to $40.00. Private physicians in conjunction with reference laboratories also provide testing at varying costs. Routine testing is also performed at all blood collection centers and donor banks, but these are not considered public screening sites.

The Montrose Clinic Alternate Test Site was established to provide a testing facility where persons concerned about possible exposure to the AIDS virus could be tested away from the blood bank setting. The clinic provides pre- and post-test counseling for all clients. No names are taken and no personal identifiers are kept. Each client is given a number and must return a week later, in person, for test results and counseling. Since December 1986 a more detailed, but still anonymous, questionnaire has been implemented to assess risks and the demographics of those tested. For the purpose of testing, the risk categories are: homosexual/bisexual males, intravenous (IV) drug users, homosexual/bisexual males who also use IV drugs, heterosexual partners of the above categories, and others (low risk).

Antibodies (HIV) have been detected in 30% of the high-risk persons and 3% of the low-risk persons tested at the Montrose Clinic. This rate is based on 3,999 high-risk people and 1,081 low-risk people tested since mid-1985. In recent months, the clinic has noticed a large increase in the number of heterosexuals interested in knowing their antibody status. Some are past or current sexual partners of people at risk for AIDS, including heterosexual contacts of female prostitutes. Others do not report any known risks and represent sexually active heterosexuals who are worried about exposure to the virus. Results and a description of those seeking the test since December 1986 are presented in Table 3. This table does not represent the overall seropositivity reported above, only a selected two month period of testing.

The HIV antibody prevalence at blood collection centers in Houston represents another, yet quite different segment of the population. Since June 1985, all local blood banks have tested every unit of donated blood for the HIV antibody. Previous to this testing, voluntary deferral programs were implemented to strongly discourage high-risk individuals from donating blood. This deferral program includes a questionnaire in addition to a confidential way of designating whether the donation should be used for transfusion or for research. Both the voluntary deferral system and the donor designation are still utilized in conjunction with HIV antibody testing.

From June 1985 to December 1986, one large local blood collection center had tested 296,023 units of blood. Of the 294,987 units designated by the donors to be used for transfusion, 151 or 0.05% were HIV antibody positive. These units were destroyed and not used for transfusion. The low prevalence of 0.05% represents either rare false-positive reactions, even with Western Blot confirmation, or exposure among people who believe themselves not to be at risk for AIDS. (See Table 4.) The prevalence is higher (0.8%) among those who designated their donation to be used for research. The higher prevalence among this group is probably due to a limited number of persons who suspected that they may be at risk for AIDS, but because of circumstances (i.e. group donations) felt uncomfortable in declining to donate.

Data from these two highly selected groups of people indicates that the prevalence of HIV exposure in Houston varies greatly with the group tested. The true prevalence among the entire Houston population is probably underestimated from blood center data and overestimated by Montrose Clinic data. However, data on the actual number exposed in the general population is unknown. Estimates by the CDC are that 1 to 2 million people may be infected in the United States.

Education

In the fight against AIDS, the most powerful weapon is education. Care must be taken, however, to be extremely efficient and deliberate in these educational efforts. Given the magnitude of the challenge to educate, billions of dollars could easily be wasted by trying to deliver the critical information through ineffective means that produce little or no impact. There is an unfortunate trend for every involved group to have their own AIDS information pamphlet carrying their own logo. The growth of this "vanity press" activity should not be funded by taxpayers' dollars. Instead, the minimum requirements for printed material could be met by a limited number of brochures or booklets that are closely reviewed by scientific, educational, and advertising panels, then endorsed by a limited number of highly respected national organizations, such as the U.S. Public Health Service or the National Red Cross.

A critical issue is to balance the information in the educational messages. Some are of the opinion that they should "scare the hell out of the public". Unfortunately, many simply ignore messages that are perceived to be overly dramatic or shocking. An example from the past is when teenagers were shown the bloody details of motor vehicle accidents in order to scare them into becoming safe drivers. It didn't produce the desired effect, as documented by post-screening surveys.

With AIDS, there is a risk of not only numbing the intended target audience, but also provoking completely unproductive reactions. A situation recently occurred in Houston where, for very different reasons, gay community advocates and very conservative political advocates both began sounding an alarm that AIDS was going to "spread like wildfire" through the heterosexual population. One group's solution was to have government spend more money on AIDS programs. The other group's solution was to lock up all persons in high-risk groups.

The first tangible proposal by this second group was to reinstitute health cards for all foodhandlers in Houston. Given the cost of such testing, the number of foodhandlers, and the proposed schedule of testing, the cost to consumers was estimated to have been $33 million per year in Houston alone. Therefore, the Health Department's first major educational challenge was to accurately and convincingly assure elected officials and the public that AIDS is not spread by casual contact.

The following presentation of the key epidemiologic data was used to convince a vast majority of Houstonians that AIDS is not spread by casual contact. First, the major risk groups in the national case series are described and how sexual behaviors, IV drug use, and transfusions were indeed the most probable risk factors for 96.8% of all 33,720 reported cases. Second, attention was focused on the miscellaneous risk category of cases whose risk factors were designated as "Other/Unknown at this time".

As of April 6, 1987 a total of 1,053 no identified risk (NIR) cases were in this category. Since 1981, 1,621 cases have been initially reported with no identified risk factor. Of these, 568 were reclassified to an official risk group when further information was obtained. The remaining cases (1053) were listed as NIR. Within that group, 236 cases could not be interviewed. They either refused the interview, or died, or became lost to follow-up before an interview could be conducted. Of the remaining 817 cases, 595 were still under study and awaiting an interview. This left 222 cases that have been interviewed. Approximately 102 of these reported multiple sexually transmitted disease (STD) and/or sexual contact with prostitutes. While this does not put them into an official high-risk group, it does indicate a history of multiple sexual partners. The remaining 120 cases reported no behaviors to account for their having AIDS. This could be because they do not know the history of all their sexual partners for the last 5 to 7 years; any of whom could have been infectious. These NIR cases represent only 0.4% (120/33,245 adult cases) of the total adult case series. This data has proved to be very effective in convincing the public that AIDS is not spread by casual contact.

Variations of this presentation have been presented to a subcommittee of Houston City Council, dozens of groups of health professionals, administrators and nurses of the majority of schools in the city's largest school district, employee groups of numerous local companies, and dozens of church groups. A weekend feature highlighting this data was published in one of the daily newspapers along with regular updates on AIDS in both major local newspapers. Apparently, the message that AIDS cannot be spread by casual contact has taken hold in Houston, since issues similar to the health card initiative have not resurfaced in more than two years.

The other part of health education is going to be much more difficult. This challenge is to educate all segments of the population who are sexually active on how to avoid or minimize the risk of acquiring AIDS. Sending a safe-sex brochure to every Houstonian over the age of 18 will not be effective. Instead, efforts should be placed in public service announcements on television and radio, backed up by information hotlines and a carefully selected inventory of brochures. To reach teenagers who are becoming sexually active, health education programs in school need to incorporate segments on how to avoid exposure to the AIDS virus. Programs are being implemented by local school districts and the largest district is involving epidemiologists from the Health Department in the development of these programs. These efforts through mass media and in the schools present the best chances of limiting the spread of this disease in Houston.

Services for People with AIDS and ARC in Houston

The City of Houston by law cannot provide medical care to anyone. The responsibility of medical care has been mandated by state charter to the Harris County Hospital District. Thus, all indigent care for Harris County residents is provided by Ben Taub General Hospital and Jefferson Davis Hospital. These two hospitals currently provide in-patient care for AIDS and ARC patients who are without funds. Other patients with AIDS who have insurance are cared for at many of Houston's private hospitals. Out-patient care, social services, and information and referral is provided by many agencies in Houston.

- AID for AIDS
  - direct financial assistance
- AIDS FOUNDATION OF HOUSTON
  - information hotline/referral
  - social services
  - educational programs (speaker's bureau)
  - guidelines for school district
- AIDS FOUNDATION WITH MONTROSE COUNSELING CENTER - SPECIAL PROJECT
  - risk reduction
  - disease prevention
  - volunteer training
- AIDS LEGAL HOTLINE
  - legal information and referral
- AMERICAN RED CROSS
  - educational material
- AMERICAN SOCIAL HEALTH ASSOCIATION
  - AIDS brochures
- GULF STATES HEMOPHILIA FOUNDATION
  - information and referral
- GULF COAST REGIONAL BLOOD CENTER
  - information and referral
- HARRIS COUNTY HEALTH DEPARTMENT
  - information and referral
  - disease reporting
  - guidelines for HIV infections in school/workplace/pregnancy
- HARRIS COUNTY HOSPITAL DISTRICT
  - medical care for the indigent
- HARRIS COUNTY SOCIAL SERVICES
  - counseling and referral
  - interim financial assistance for disabled with AIDS/ARC
- HOUSTON AIDS COALITION
  - interagency networking and grants
- HOUSTON CRISIS HOTLINE
  - information and referral for teens with drug concerns

BERING DENTAL CLINIC
- basic dental health services for indigent AIDS patients

CANCER INFORMATION SERVICE
- information and referral

THE CHILDREN'S HOME
- hospice for children (AIDS/ARC)

CITY OF HOUSTON DEPARTMENT OF HEALTH AND HUMAN SERVICES
- information and referral
- disease reporting
- educational programs and materials
- guidelines for HIV infection in school/workplace/pregnancy

CLERGY CONSULTATION ON AIDS
- spiritual needs
- in-home hospice care
- provider relief
- support groups for patients
- bereaved relief

FAMILY SERVICE CENTER
- individual and group counseling
- homemaking services

GAY AND LESBIAN SWITCHBOARD OF HOUSTON
- information and referral
- telephone counseling

INSTITUTE FOR IMMUNOLOGICAL DISORDERS
- research and treatment protocols

MAYOR'S TASK FORCE ON AIDS
- issues and interagency networking

MONTROSE CLINIC
- medical information/referral
- AIDS antibody test (anonymous)
- PACE Program (testing of immune status)
- education

MONTROSE COUNSELING CENTER
- individual and group counseling
- referral

OMEGA HOUSE
- AIDS hospice

UNITED WAY
- information and referral

VISITING NURSE ASSOCIATION
- home care for AIDS patients
- counseling and support services

Table 1

Comparison of Transmission Categories
Houston SMSA vs. Other U.S. Cases
January 1980 through April 6, 1987

Risk Factor	Houston Cases Number	Houston Cases Percent	Other U.S. Cases Percent
Homosexual/Bisexual Male	943	83.1%	64.2%
I.V. Drug User	19	1.7%	17.0%
Homo/Bisexual Male and IV Drug User	113	10.0%	7.5%
Hemophiliac	0	0.0%	1.0%
Heterosexual Cases	11	1.0%	3.9%
Transfusion Recipient	15	1.3%	2.1%
Parent at Risk for AIDS	5	0.4%	1.1%
Other/Unknown at this time	29	2.5%	3.2%

Table 2

Reported Cases of AIDS and Percent Increase
by Year of Diagnosis

Houston SMSA, January 1980 to 1986

Year of Diagnosis	Number of Cases	Percent Increase
1980	1	
1981	7	600%
1982	18	157%
1983	77	327%
1984	174	126%
1985	323	86%
1986	469	45%

Table 3

Montrose Clinic HIV Testing
December 1, 1986 to March 31, 1987

Risk Category	Number of HIV Tests Male	Number of HIV Tests Female	HIV Test Results Male Pos	HIV Test Results Male Neg	HIV Test Results Female Pos	HIV Test Results Female Neg
Homosexual/Bisexual Males	920	--	290	630	--	--
Intravenous (IV) Drug Users	112	87	4	108	5	82
Homosexual/Bisexual Males Who are also IV Drug Users	143	--	76	67	--	--
Heterosexual Partners of the Above Groups	147	180	3	144	1	179
Others (low risk)	279	212	17	262	4	208
Total	1601	479	390	1211	10	469

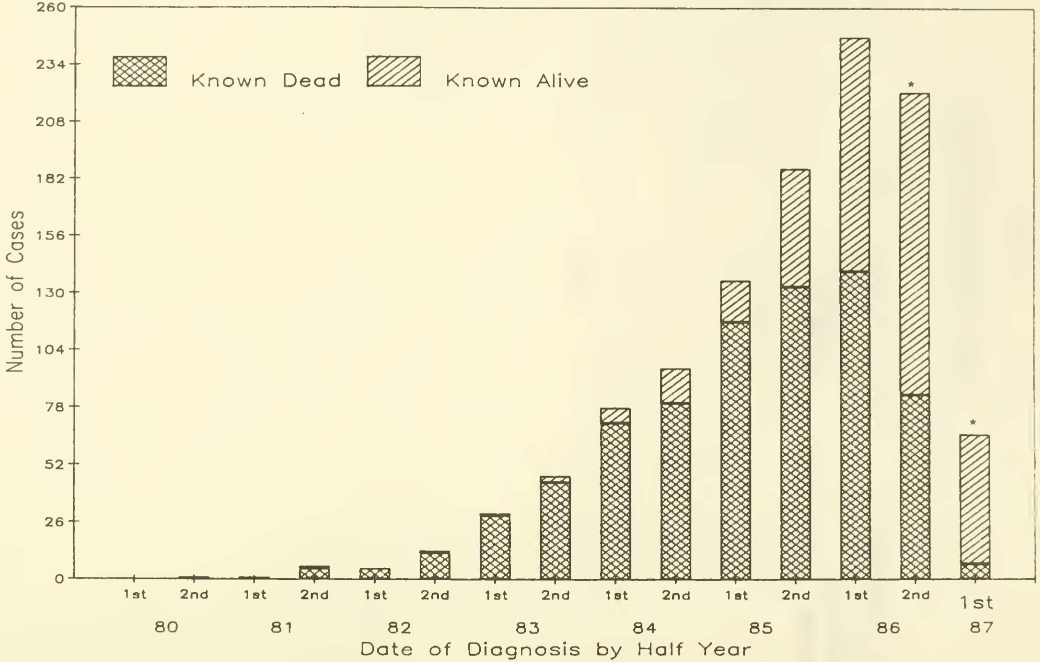
Table 4

Blood Bank HIV Testing
June 1985 to December 1986

Donor Designation	Number of Units Donated	HIV Positive
Transfusion	294,987	151 (0.05%)
Research	1,036	8 (0.8%)
Total	296,023	159

FIGURE 1

AIDS Cases in the Houston SMSA
January 1, 1980 to April 6, 1987



* Incomplete due to lag between diagnosis and reporting

ATTACHMENT A

AIDS INFORMATION UPDATE: APRIL 1987

This month's report shows the addition of 57 cases of confirmed AIDS in the Houston area over last month. Among the additions, there are two new cases due to transfusions and two new pediatric cases due to parents being at risk for AIDS.

Two New Cases of Transfusion-Associated AIDS

Both cases occurred in Houston area women who received blood components in late 1982 and early 1983. This was prior to the implementation of stringent screening procedures for AIDS which have been in effect at all U.S. blood banks since the spring of 1985. One white female was over 60 years of age and received six units of red blood cells in early 1983. Four years later, she developed an opportunistic infection diagnostic of AIDS and expired. She was HIV antibody positive. One of the six donors reported a history of homosexual activity. The second patient is an Hispanic female in her twenties and has no other risks for AIDS except receiving two units of red blood cells in late 1982. Three and one half years after these transfusions, she was diagnosed with AIDS and was HIV antibody positive. To date, a specific donor at risk for AIDS has not been identified.

Transfusion-associated cases are those in which no risk factors for AIDS are identified other than receiving blood products via transfusion. When these cases are reported, the Bureau of Epidemiology investigates transfusion-associated AIDS cases to identify any donors at risk for AIDS. In order to rule out a transfusion as the source of infection, all donors must be found to be HIV antibody negative. If any of the donors cannot be located or tested, then a case is still considered transfusion-associated in the absence of other risks for AIDS.

Two New Cases of Pediatric AIDS

One of the new pediatric cases is a white male child under the age of three whose mother now has AIDS. The child showed signs of illness within the first four months of life, was confirmed with AIDS one year later, and expired. The mother was diagnosed with *Pneumocystis carinii* pneumonia late last year and is HIV antibody positive. She has been interviewed and reports no risks for AIDS other than heterosexual contact. Although there is no direct evidence, it is probable that she was exposed through heterosexual contact.

The second new pediatric case involves an Hispanic female child under the age of five whose parents are both at risk for AIDS. The child did not show signs of illness until the fourth year of life and was diagnosed with an opportunistic infection of AIDS. She is still living. The father of the child reported a history of IV drug use but was HIV antibody *negative* at latest testing. All the siblings in the family are HIV antibody negative. The mother, however, was transfused one month before delivery (in 1982) with two units of red blood cells and is HIV antibody positive. The "Look-Back" Program undertaken by blood collection centers has identified one of her donors as HIV antibody positive.

Monthly Summary from Houston AIDS Registry

The data as of April 6, 1987 is attached.

Houston Deparment of Health and Human Services
Bureau of Epidemiology
(713) 222-4271

AIDS SURVEILLANCE REPORT
HOUSTON DEPARTMENT OF HEALTH AND HUMAN SERVICES
BUREAU OF EPIDEMIOLOGY
April 6, 1987

LOCATION[1]	# CONFIRMED CASES CUMULATIVE[2]	# SUSPECT CASES CUMULATIVE[3]	TOTAL
Houston	960	360	1320
Harris Co. (Non-Houston)	123	49	172
TOTAL	1083	409	1492
Montgomery County	7	2	9
Fort Bend County	19	9	28
Brazoria County	18	5	23
Liberty County	6	1	7
Waller County	2	0	2
SMSA CASE LOAD	1135	426	1561

SOURCE OF REPORT	CASES	PERCENT OF TOTAL
Hospital	860	76
Physician	166	14
State Health Dept	42	4
Vital Statistics	35	3
National (CDC)	19	2
Other agencies	13	1
Total	1135	100%

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[1] Location determined by residency at onset of illness suggestive of AIDS.
[2] Confirmed cases meet the Centers for Disease Control (CDC) definition for an AIDS case.
[3] Suspect cases are patients with conditions suggestive of AIDS but do not meet the CDC definition, or people with the preliminary signs and symptoms of AIDS.

Acquired Immunodeficiency Syndrome (AIDS)
Cases of AIDS Meeting the CDC Surveillance Definition
Surveillance Report - 04/06/87

HOUSTON SMSA

1. Disease Category	Adult/Adolescent Cases (%)	Adult/Adolescent Deaths (%)	Pediatric Cases (%)	Pediatric Deaths (%)	Total Cases (%)	Total Deaths (%)
KS without PCP	200 (18)	129 (65)	0 (0)	0 (.)	200 (18)	129 (65)
Both KS and PCP	119 (11)	91 (76)	0 (0)	0 (.)	119 (10)	91 (76)
PCP without KS	575 (51)	346 (60)	2 (25)	2 (100)	577 (51)	348 (60)
OI without KS or PCP	233 (21)	158 (68)	6 (75)	2 (33)	239 (21)	160 (67)
Total	1127 (100)	724 (64)	8 (100)	4 (50)	1135 (100)	728 (64)

2. Age	Cases (%)
Under 13	8 (1)
13-19	1 (0)
20-29	307 (27)
30-39	576 (51)
40-49	177 (16)
Over 49	66 (6)
Unknown	0 (0)
Total	1135 (100)

3. Race/Ethnicity	Adult/Adolescent Cases (%)	Pediatric Cases (%)	Total Cases (%)
White, Not Hispanic	889 (79)	4 (50)	893 (79)
Black, Not Hispanic	123 (11)	3 (38)	126 (11)
Hispanic	112 (10)	1 (13)	113 (10)
Other	3 (0)	0 (0)	3 (0)
Unknown	0 (0)	0 (0)	0 (0)
Total	1127 (100)	8 (100)	1135 (100)

4. Patient Groups	Adult/Adolescent Males (%)	Adult/Adolescent Females (%)	Total (%)
Homosexual or bisexual Men	943 (85)	0 (0)	943 (84)
Intravenous (IV) drug User	14 (1)	5 (22)	19 (2)
Homo/Bi IV drug User	113 (10)	0 (0)	113 (10)
Hemophiliac	0 (0)	0 (0)	0 (0)
Heterosexual contact	1 (0)	9 (39)	10 (1)
Born in NIR Country *	1 (0)	0 (0)	1 (0)
Transfusion with blood/products	7 (1)	5 (22)	12 (1)
None of the above/Other	25 (2)	4 (17)	29 (3)
Total	1104 (100)	23 (100)	1127 (100)

	Pediatric Males (%)	Pediatric Females (%)	Total (%)
Hemophiliac	0 (0)	0 (0)	0 (0)
Parent at risk/has AIDS	3 (100)	2 (40)	5 (63)
Transfusion with blood/products	0 (0)	3 (60)	3 (38)
None of the above/Other	0 (0)	0 (0)	0 (0)
Total	3 (100)	5 (100)	8 (100)

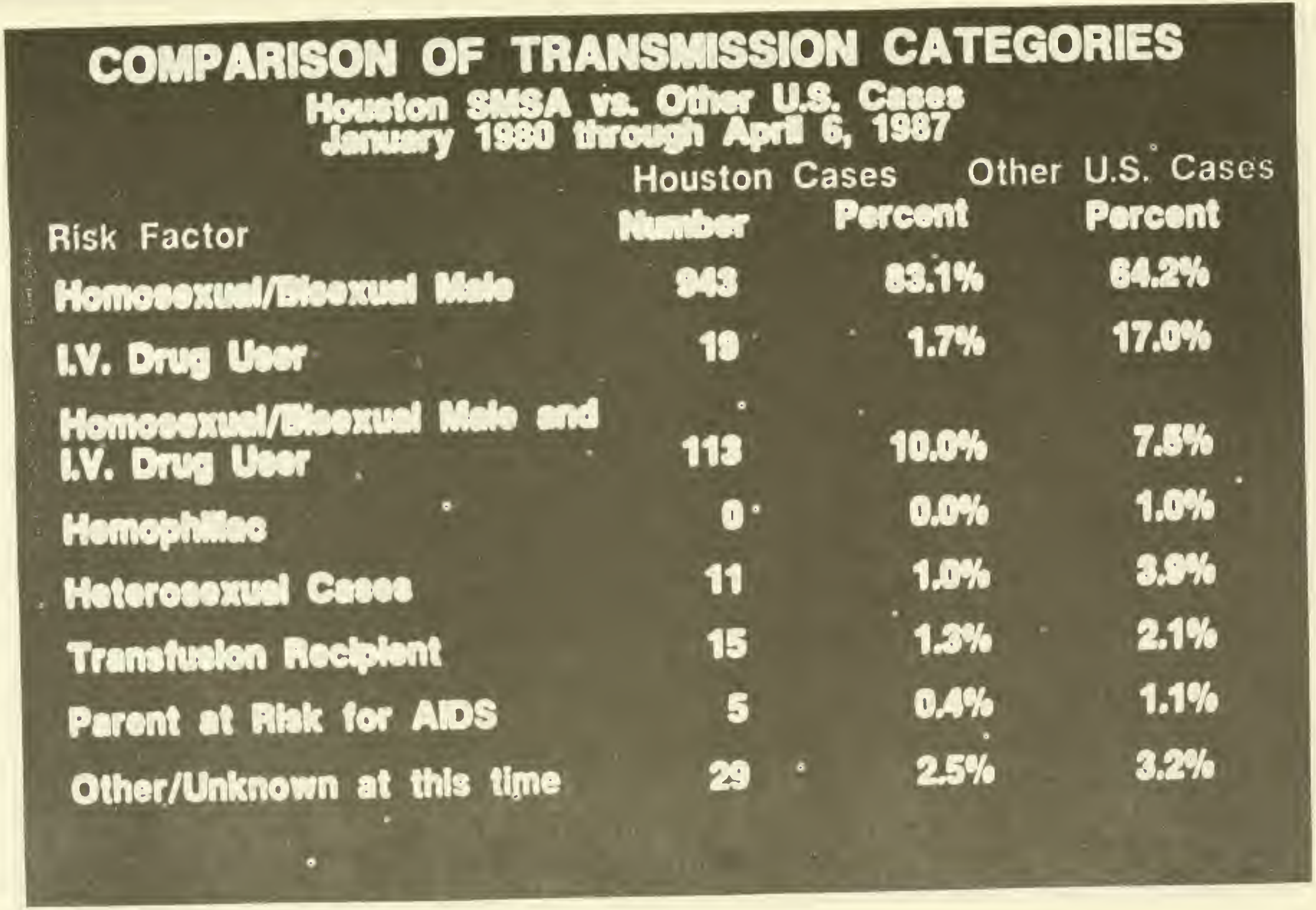
* Haiti or Africa: considered heterosexual contact

Acquired Immunodeficiency Syndrome (AIDS)
Cases of AIDS Meeting the CDC Surveillance Definition
Surveillance Report - 04/06/87

HOUSTON SMSA

5. Reported Cases of AIDS and Case-Fatality Rates by Half-Year of Diagnosis.

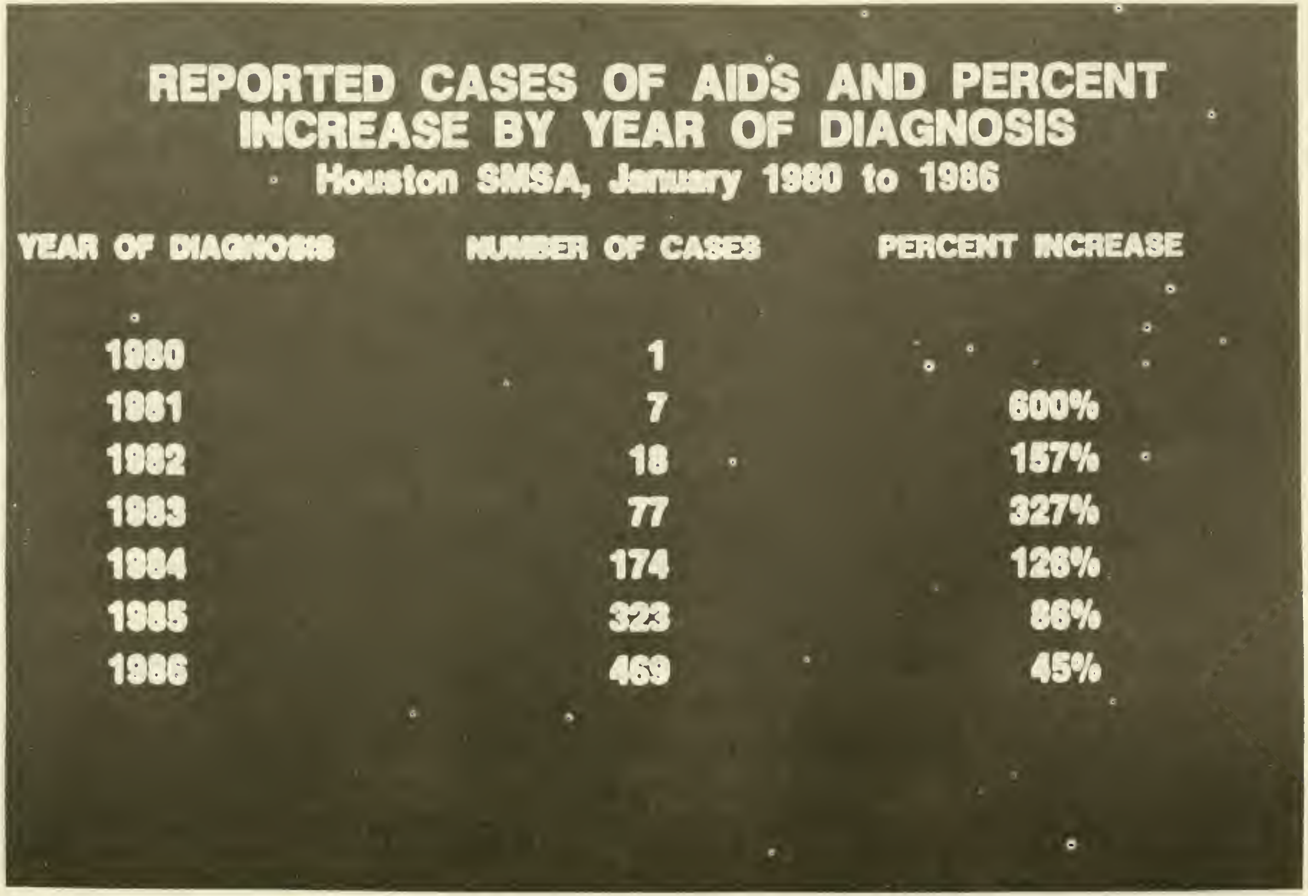
Half-Year of Diagnosis	Number of Cases	Number of Deaths	Case-Fatality Rate
Before 1980	0	0	—
1980 Jan -June	0	0	—
July-Dec	1	1	100%
1981 Jan -June	1	1	100%
July-Dec	6	5	83%
1982 Jan -June	5	5	100%
July-Dec	13	12	92%
1983 Jan -June	30	29	97%
July-Dec	47	44	94%
1984 Jan -June	78	71	91%
July-Dec	96	80	83%
1985 Jan -June	136	117	86%
July-Dec	187	133	71%
1986 Jan -June	247	140	57%
July-Dec	222	83	37%
1987 Jan -Apr 6	66	7	11%
Totals	1135	728	64%



COMPARISON OF TRANSMISSION CATEGORIES

Houston SMSA vs. Other U.S. Cases
January 1980 through April 6, 1987

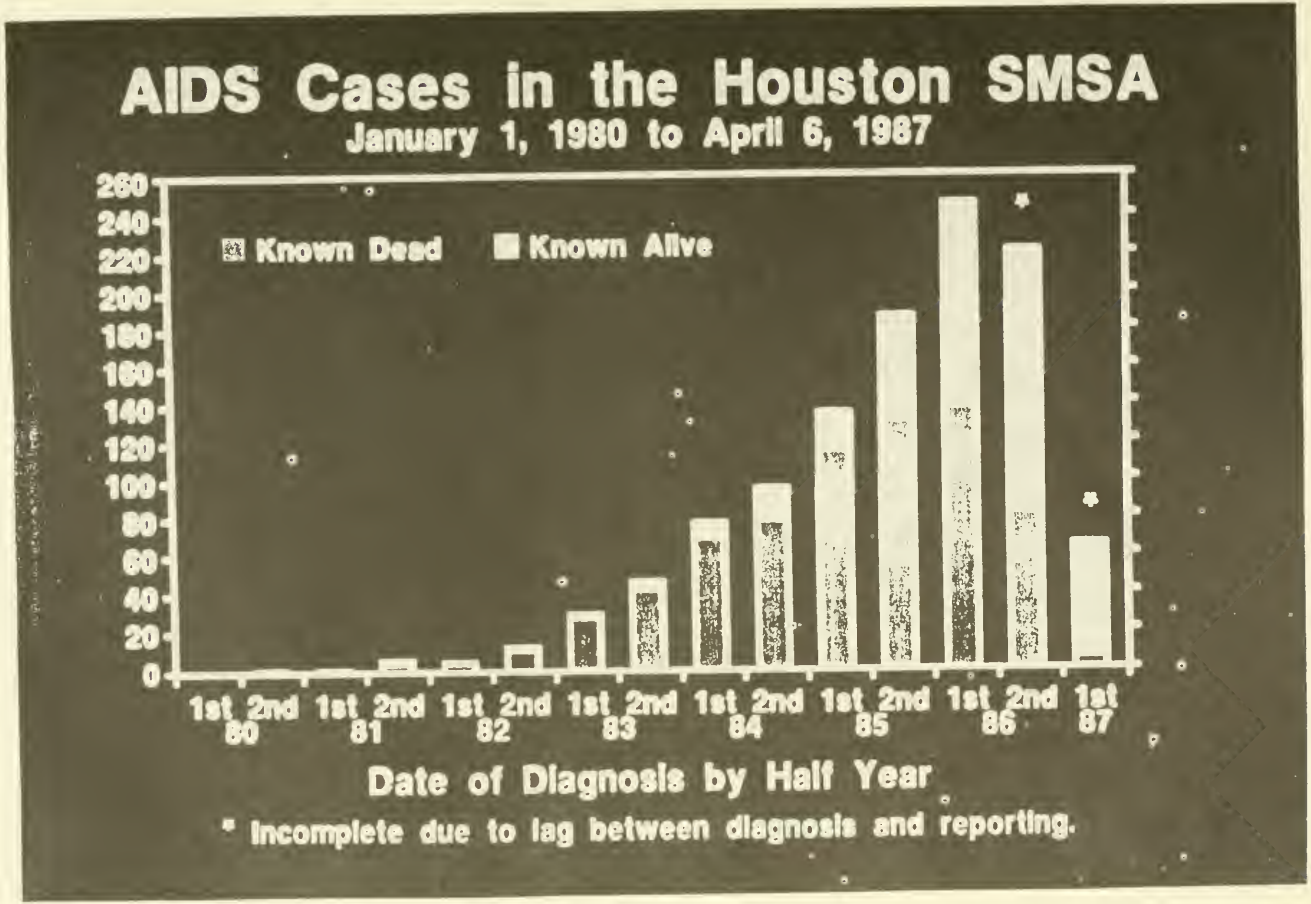
Risk Factor	Houston Cases Number	Houston Cases Percent	Other U.S. Cases Percent
Homosexual/Bisexual Male	943	83.1%	64.2%
I.V. Drug User	19	1.7%	17.0%
Homosexual/Bisexual Male and I.V. Drug User	113	10.0%	7.5%
Hemophiliac	0	0.0%	1.0%
Heterosexual Cases	11	1.0%	3.9%
Transfusion Recipient	15	1.3%	2.1%
Parent at Risk for AIDS	5	0.4%	1.1%
Other/Unknown at this time	29	2.5%	3.2%



REPORTED CASES OF AIDS AND PERCENT INCREASE BY YEAR OF DIAGNOSIS

Houston SMSA, January 1980 to 1986

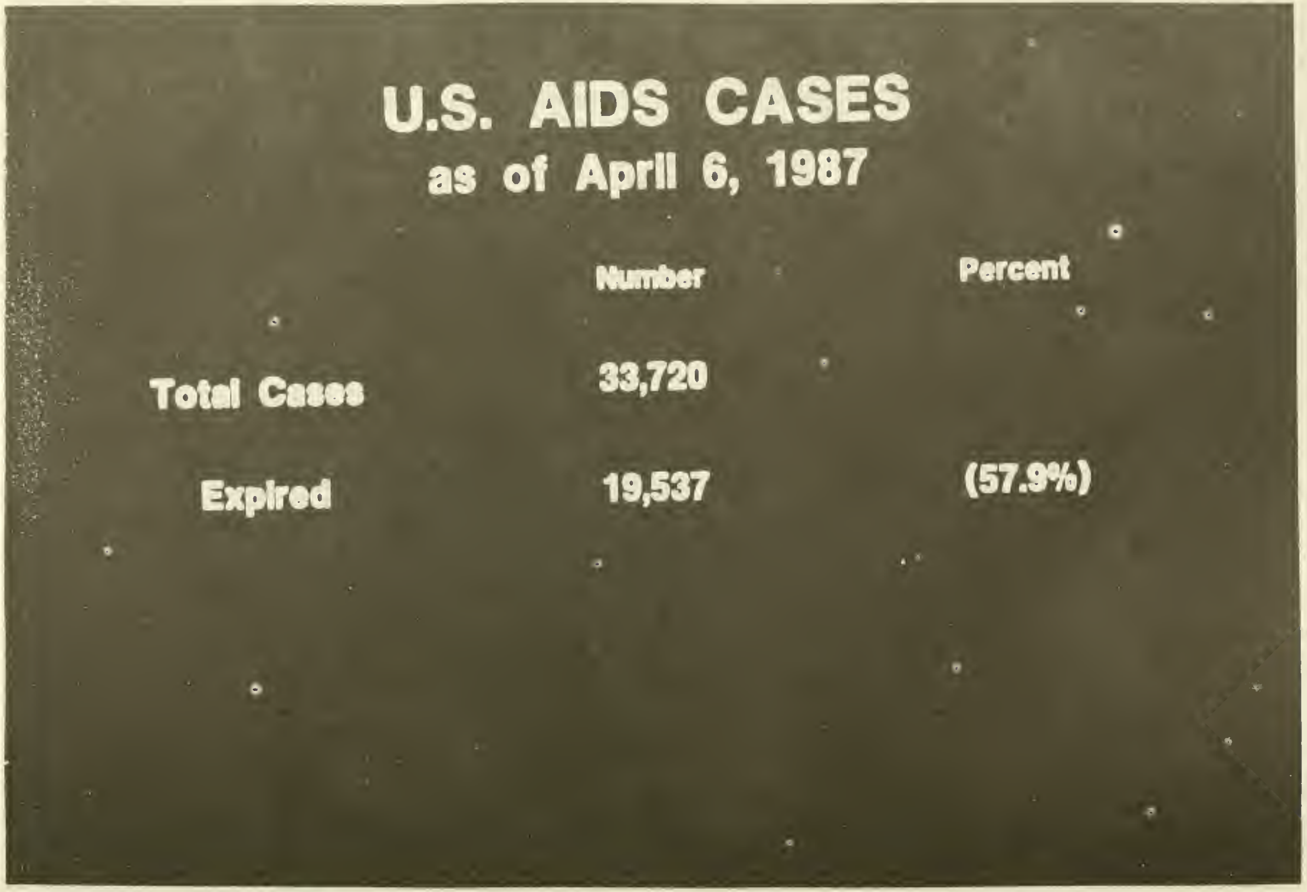
YEAR OF DIAGNOSIS	NUMBER OF CASES	PERCENT INCREASE
1980	1	
1981	7	600%
1982	18	157%
1983	77	327%
1984	174	126%
1985	323	86%
1986	469	45%



AIDS Cases in the Houston SMSA

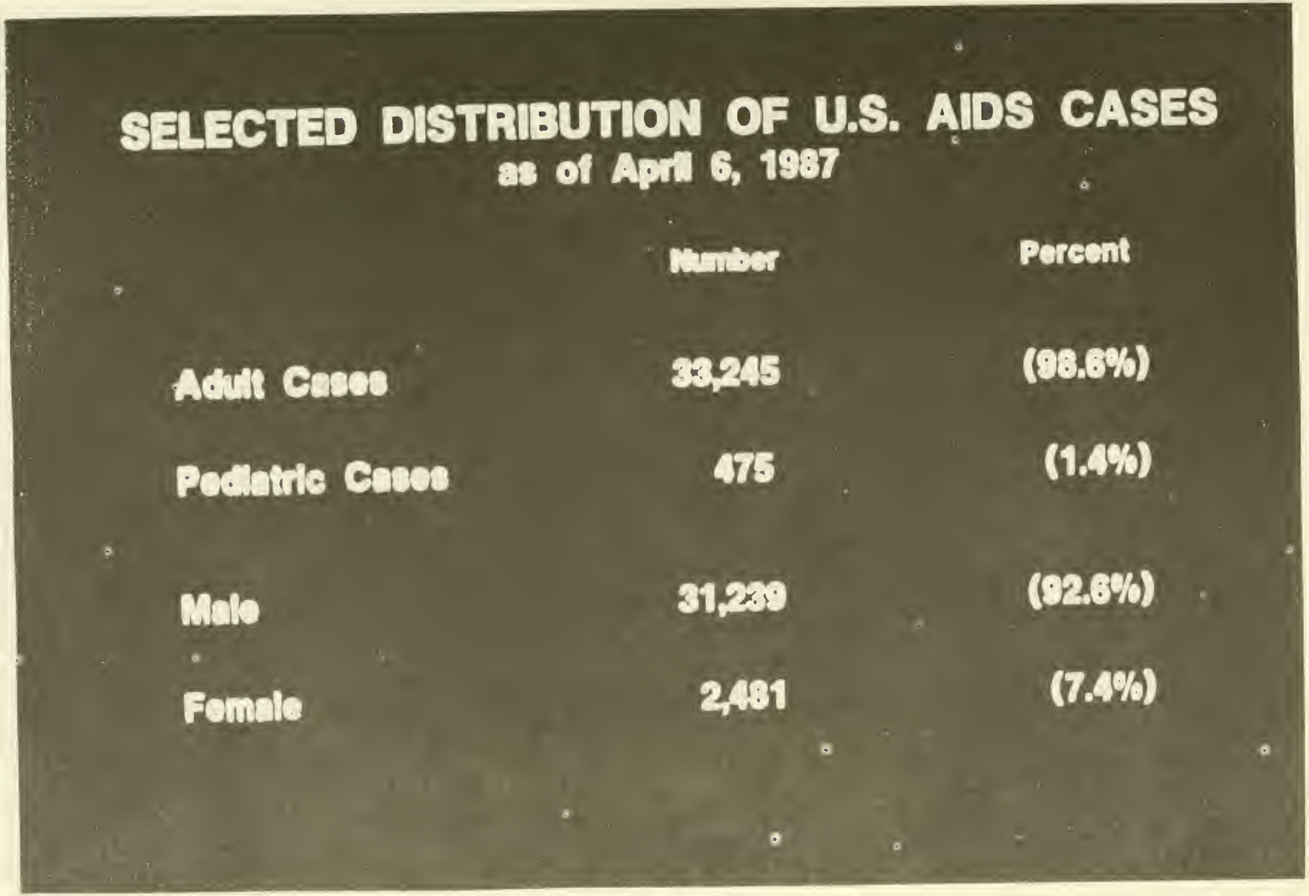
January 1, 1980 to April 6, 1987

* Incomplete due to lag between diagnosis and reporting.



U.S. AIDS CASES
as of April 6, 1987

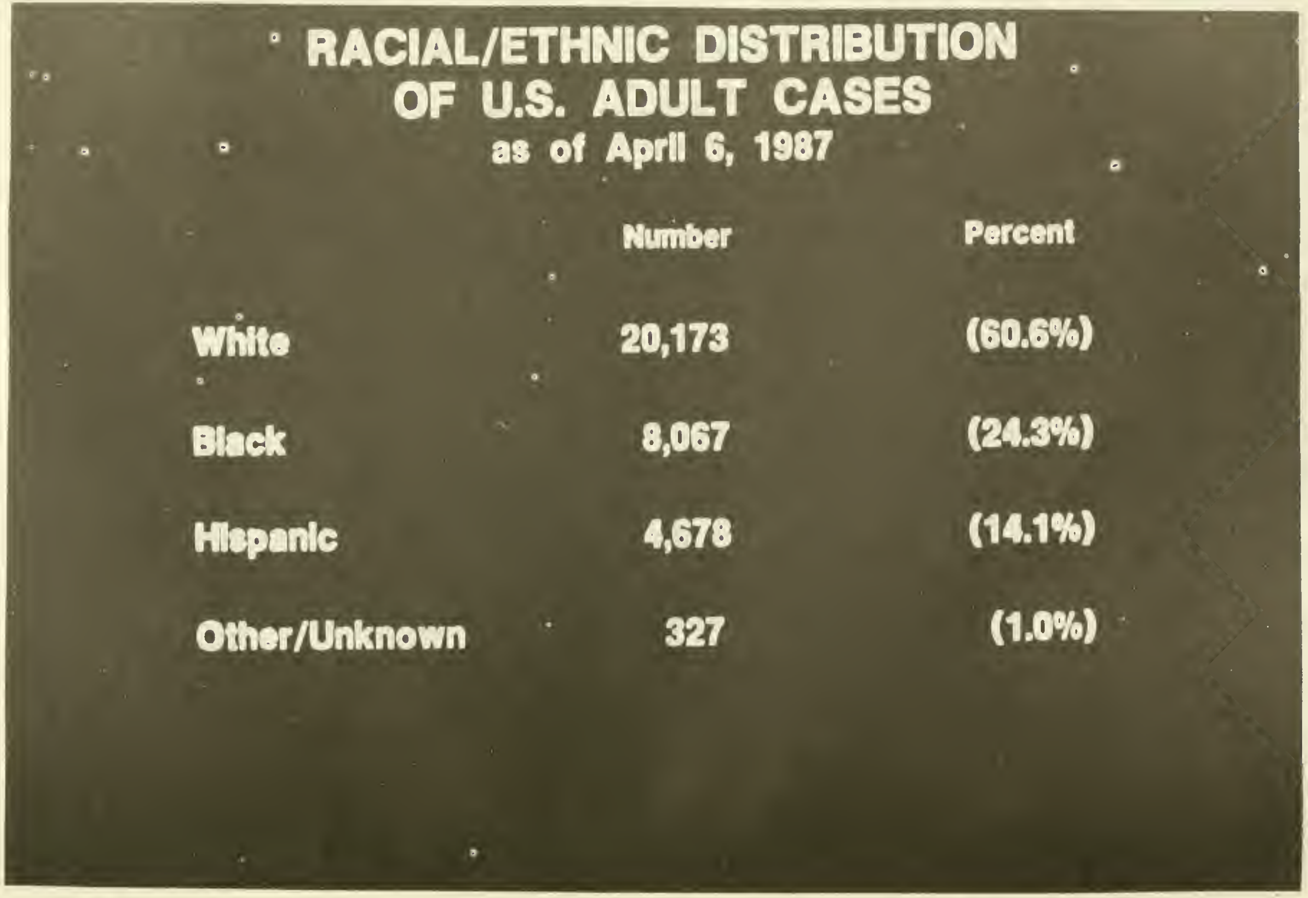
	Number	Percent
Total Cases	33,720	
Expired	19,537	(57.9%)



SELECTED DISTRIBUTION OF U.S. AIDS CASES

as of April 6, 1987

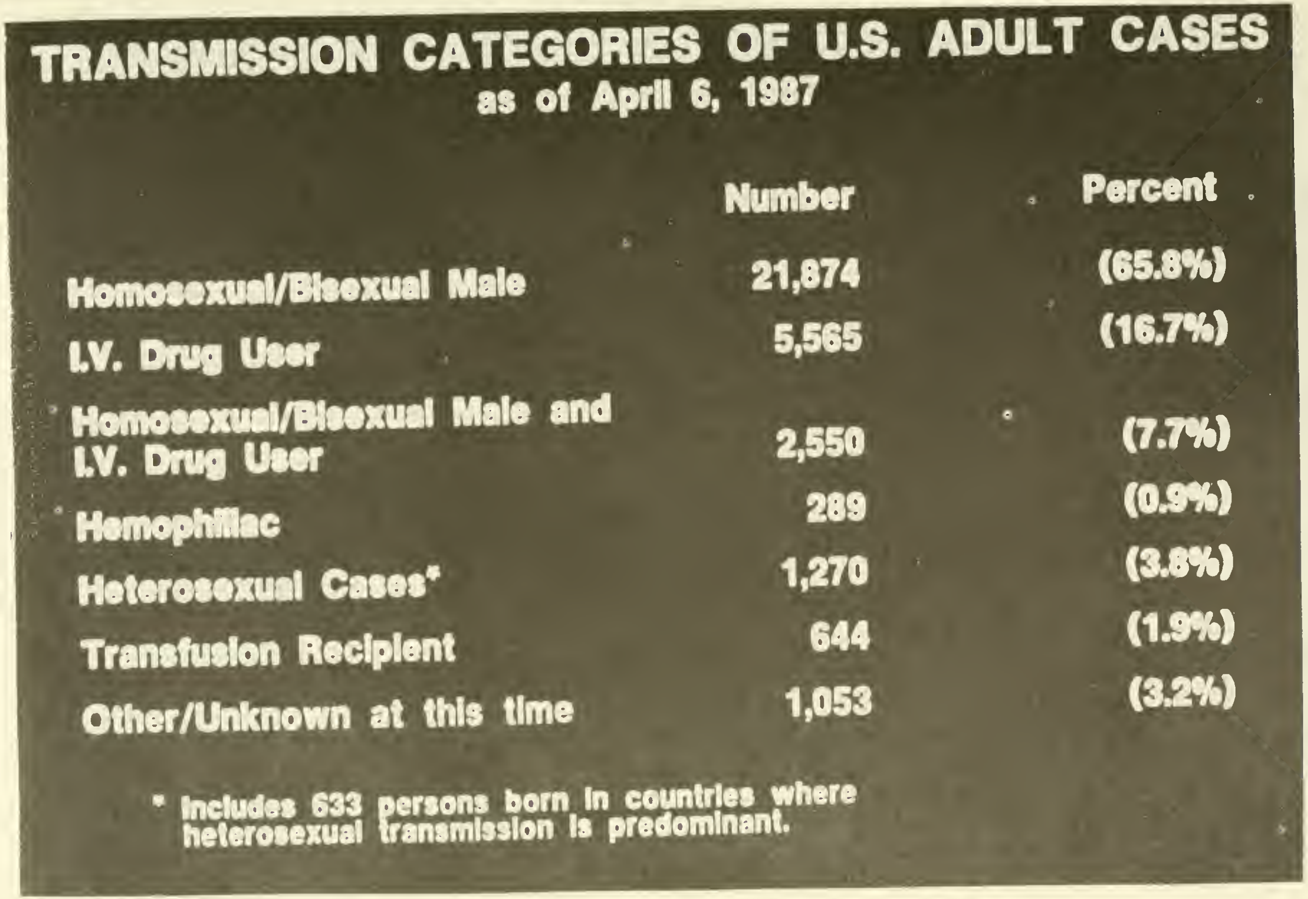
	Number	Percent
Adult Cases	33,245	(98.6%)
Pediatric Cases	475	(1.4%)
Male	31,239	(92.6%)
Female	2,481	(7.4%)



RACIAL/ETHNIC DISTRIBUTION OF U.S. ADULT CASES

as of April 6, 1987

	Number	Percent
White	20,173	(60.6%)
Black	8,067	(24.3%)
Hispanic	4,678	(14.1%)
Other/Unknown	327	(1.0%)



TRANSMISSION CATEGORIES OF U.S. ADULT CASES

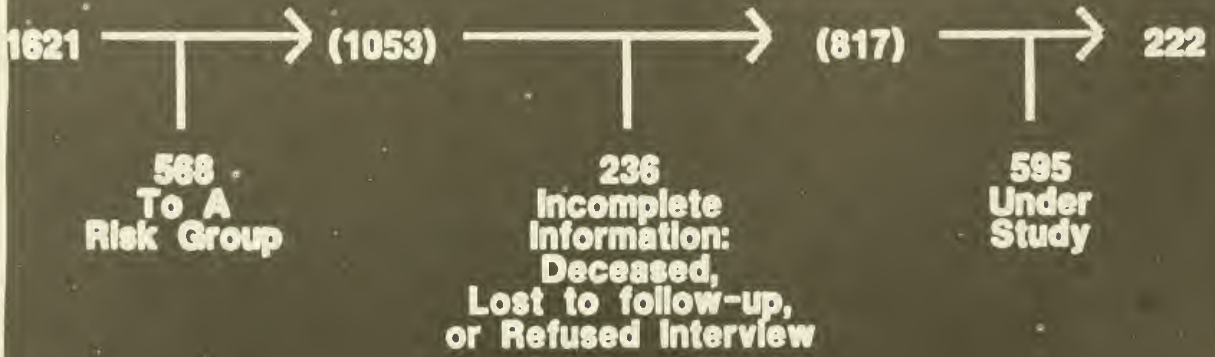
as of April 6, 1987

	Number	Percent
Homosexual/Bisexual Male	21,874	(65.8%)
I.V. Drug User	5,565	(16.7%)
Homosexual/Bisexual Male and I.V. Drug User	2,550	(7.7%)
Hemophiliac	289	(0.9%)
Heterosexual Cases*	1,270	(3.8%)
Transfusion Recipient	644	(1.9%)
Other/Unknown at this time	1,053	(3.2%)

* Includes 633 persons born in countries where heterosexual transmission is predominant.

OTHER/UNKNOWN TRANSMISSION CATEGORY FOR U.S. ADULT CASES

April 6, 1987

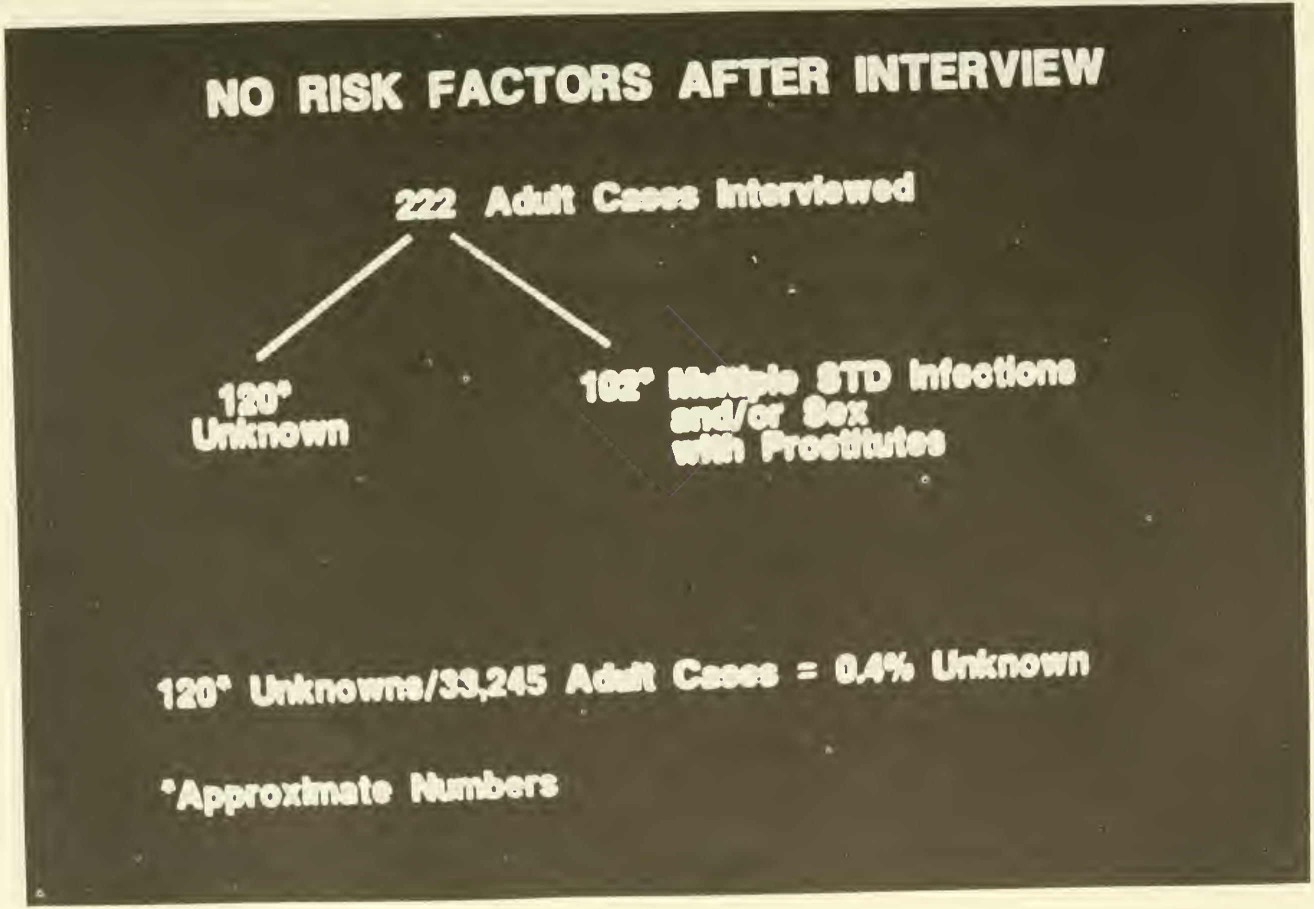


1621 → (1053) → (817) → 222

568
To A
Risk Group

236
Incomplete
Information:
Deceased,
Lost to follow-up,
or Refused Interview

595
Under
Study



NO RISK FACTORS AFTER INTERVIEW

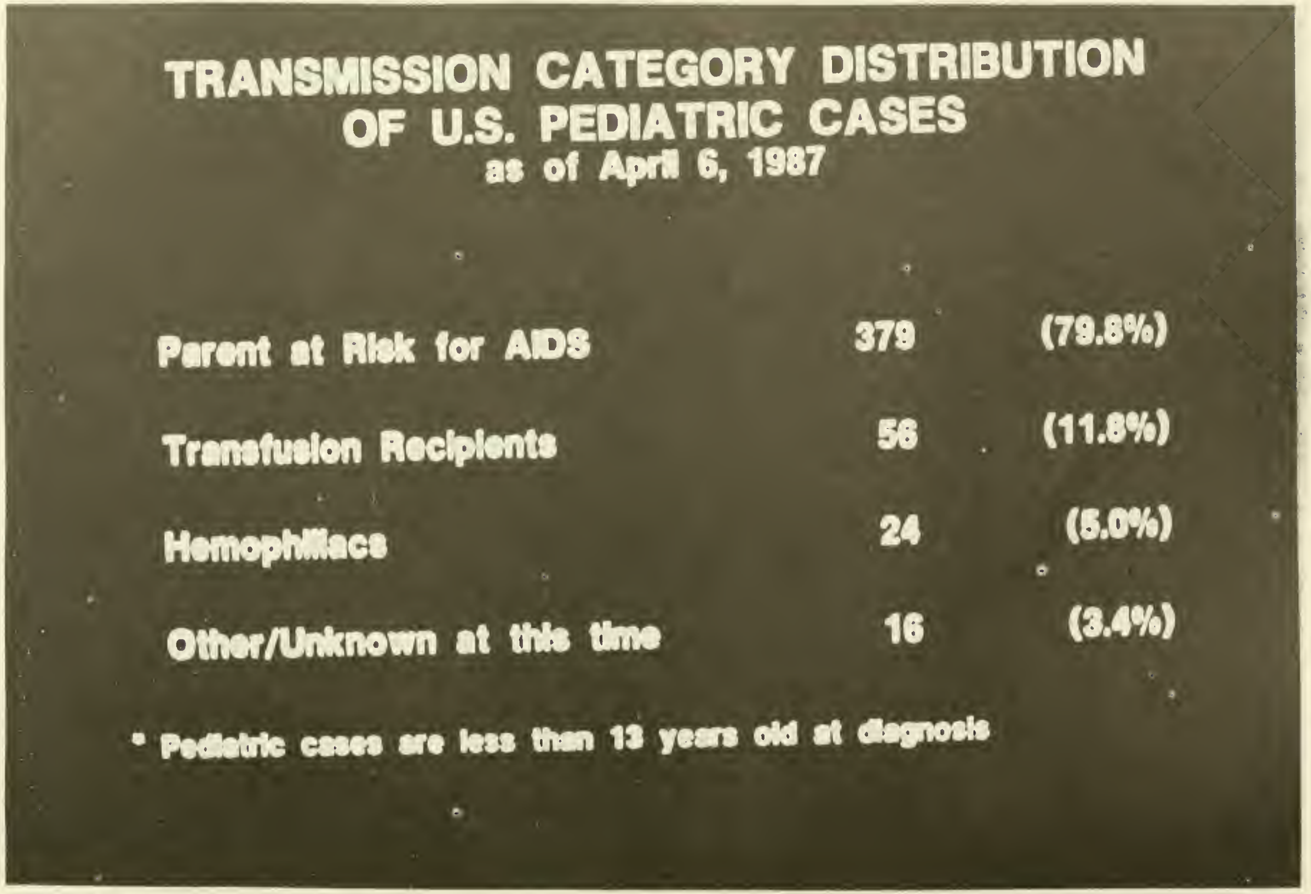
222 Adult Cases Interviewed

120*
Unknown

102* Multiple STD Infections
and/or Sex
with Prostitutes

120* Unknowns/33,245 Adult Cases = 0.4% Unknown

*Approximate Numbers

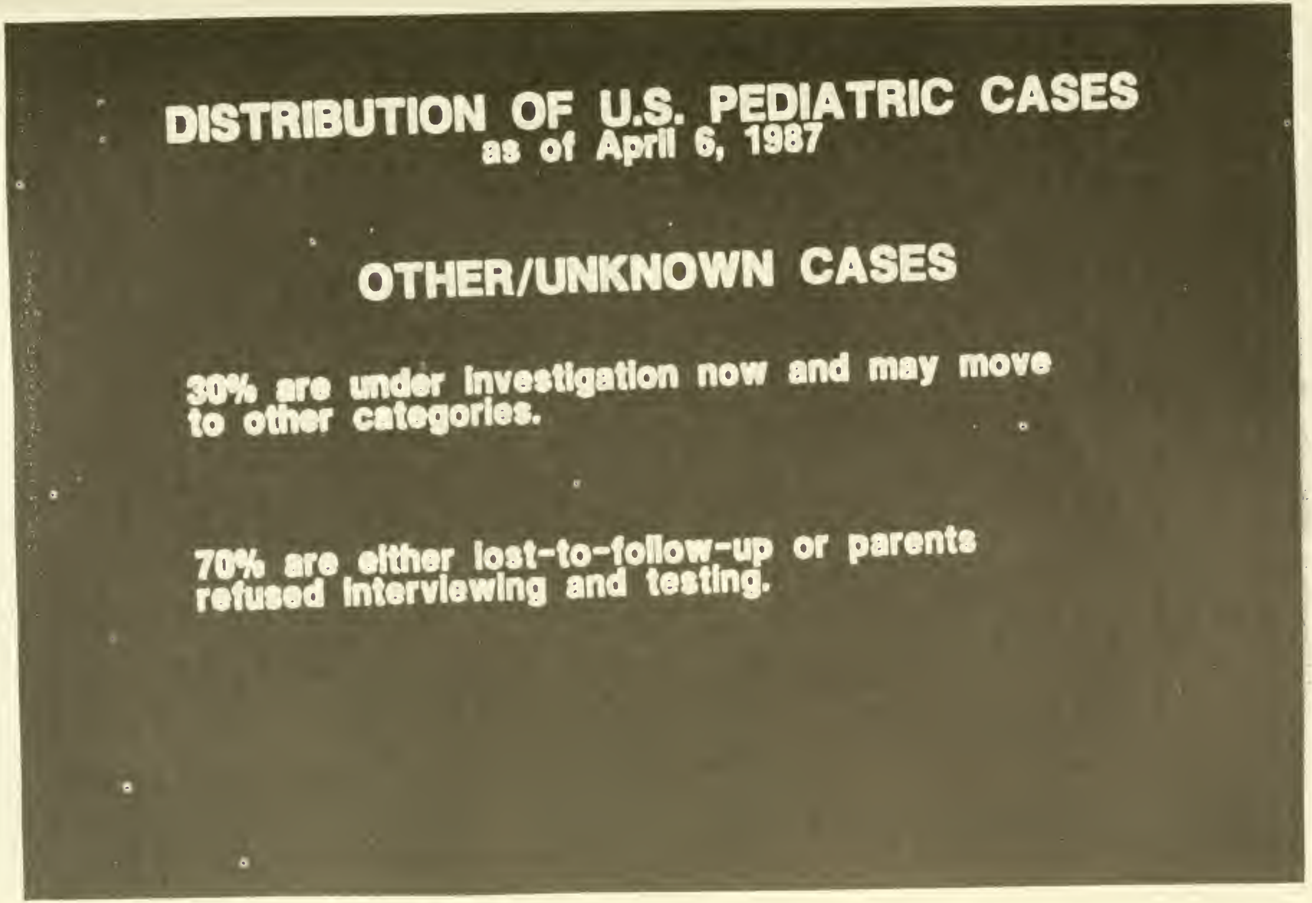


TRANSMISSION CATEGORY DISTRIBUTION OF U.S. PEDIATRIC CASES

as of April 6, 1987

Parent at Risk for AIDS	379	(79.8%)
Transfusion Recipients	56	(11.8%)
Hemophiliacs	24	(5.0%)
Other/Unknown at this time	16	(3.4%)

* Pediatric cases are less than 13 years old at diagnosis



DISTRIBUTION OF U.S. PEDIATRIC CASES
as of April 6, 1987

OTHER/UNKNOWN CASES

30% are under investigation now and may move
to other categories.

70% are either lost-to-follow-up or parents
refused interviewing and testing.

Mr. WAXMAN. Thank you very much, Dr. Haughton. Your full presentation, written presentation, will be part of the record. I notice that it is lengthy with a number of tables and we will have an opportunity to examine that. I am sure that will be very helpful to us.

Dr. Lane, you have indicated there is a disproportionate number of AIDS cases among Black and Hispanic Americans. What accounts for that?

Mr. LANE. Sir, I think, as Dr. Haughton has mentioned, first of all, it is geographic specific and mirrors rather considerably the prevalence of intravenous drug abuse, particularly in Black and Hispanic groups is some of our large east coast communities.

But I also think that in other communities, AIDS is still something of a ticking bomb. And we feel, after discussing with our colleagues in several State health departments, that there is a, an under-education activity or situation about AIDS and its transmission all over the country, in whites as well as Blacks, but particularly in Black and Hispanic minorities.

Mr. WAXMAN. So, if we are looking at a time bomb that is going to explode on many, many people and especially the minority populations, what educational campaigns has the Public Health Service begun that is directed towards minority groups to try to stop the spread of this disease?

Mr. LANE. We look at education as being education focused to the general population, education focused towards risk groups, particularly gay and bisexual and IV drug abusers and then also one-on-one counseling. And we are trying to assist with both money and technical assistance our colleagues in State and local health departments in all of those activities. And the predominant function up to now has been, however, the one-on-one counseling. And that has perhaps not been more targeted toward minority communities than anyone else. Anyone who comes in gets those services.

We have asked the State health departments, who are our main grantees in this year's cycle of grants, to target minorities and show us their plans and show us what specific efforts they are going to do toward the Black and Hispanic communities.

Mr. WAXMAN. We have an epidemic in this country of AIDS. We have known for several years there is no vaccine and there is none, at least, for at least another decade, if you are very optimistic. So, the only way to stop the spread of the disease is through education. How much money are you sending to the States for an educational effort during this last couple of months?

Mr. LANE. Yes. Sir, I will have to provide the details for the record because our money is fragmented in direct grants for health education and prevention, grants to school districts or school State school efforts. And then we are trying to undertake a national campaign not directed to the States of general information to the public. And I would like to give you those dollar figures broken down.

Mr. WAXMAN. We would like to receive that. Let me ask Dr. Krim: You have been following the AIDS epidemic from the very beginning. And you know that education is our only way to stop the spread of this disease. How would you describe the Federal efforts in educating the public? Has it been successful? Is it on target? Are we doing what we should be doing?

Ms. KRIM. It has been late getting off the ground and I know from talking to CDC representatives, such as Dr. Lane, that the approach is the thinking of these public health officials is correct. Essentially, you know, I think they are planning to do the right thing. We have not yet at the receiving end seen the effects of the program.

Mr. WAXMAN. This is 1987. We have had this disease since 1981. Certainly, within a year after 1981, we knew that there was something happening. It was sexually transmitted. We didn't have a cure and we did not have a way to stop the spread through a vaccine. Have we not known for a good number of years

Ms. KRIM. That is right. This was the point I was making that we have known very early that this was not a gay disease: that anyone was susceptible. And we knew how the infection was transmitted. We have been, as a Nation I do not point a finger to anybody in particular we have had a reaction of denial to this situation. We have not been particularly compassionate or interested in the first sufferers of AIDS. And we have wasted time. There is no question.

Mr. WAXMAN. Let me ask you this. We have wasted time. We need an educational effort. What kind of educational campaign should the Federal Government begin to reach minority groups specifically?

Ms. KRIM. You know, minorities have more of the problems of everybody else across the board, not just AIDS. I do not think I think the message is the same for everybody. What minorities needs is more of everything they need. Not just the AIDS message.

Mr. WAXMAN. Dr. Haughton, what do you think we need to do? What how much money is coming at the local level for an educational effort to stop the spread of this disease?

Mr. HAUGHTON. Well, currently, we have about $100,000 from CDC for risk-reduction education. And we have used it to establish a program at the Montrose Clinic as well as to enrich our own educational activities within the Department. We have a network of seven neighborhood health centers. And we have health educators at all of them. We also have medical directors, chief nurses, and other staff at those health centers. We have trained all of that staff to add AIDS to their educational agenda.

In addition, we have been available to all groups in the city who need to hear about the problem. We have established a speaker's bureau. We have now made presentations to a large number of employee groups. Employers are beginning to call us and ask us to come make presentation to their employees.

Church groups have called us and asked us to make presentations to their congregations. I have personally conducted radio and TV shows in which the listeners can call in and get information.

Mr. WAXMAN. Do you gear any of this specifically to minority groups or do you feel that a message for the whole population is the appropriate one?

Mr. HAUGHTON. Well, we have done both. We have in our attempts to educate, made ourselves available to all of the population of Houston. When I make presentations on the radio, I seek the rock stations because that is where our young people listen. I am very concerned about the young people in our community who are about to begin sexual activity and who may be tempted to indulge in IV drug use. And I find that I can reach that population much better on the rock stations than on a news station.

Last night, for example, NBC had a national network for information and we established a call-in bank here, a phone bank so people could call in. I had four epidemiologists sitting at those phones from 6 to 9 last night. We got 9 calls. That is because the NBC station here is a news station. The people who are interested in this problem listen to rock stations and those are the stations we should be using. Those are the stations we use.

Mr. WAXMAN. Thank you very much.

Mr. LELAND. Thank you, Mr. Chairman.

Dr. Haughton, I am glad that we seem to be rather competitive at least in terms of the lesser number of minorities afflicted with this grave disease in the city of Houston. I hope indeed that we have made the point that this hearing, while it focuses on the problems of heterosexuals afflicted with the disease, as well as minorities, that we do not lose in the scope of things the problems afflicting the homosexual community.

In the city of Houston, I have been in politics and have been an elected official now for 15 years. And we go back a couple of years ago, we remember the infamous gay referendum and the problems that ensued subsequent to that and the prejudice that we had realized in the city of Houston against the homosexual population of our city. What I am concerned about is that when we hold hearings and expand on the interest of these hearings to other communities because of the facts, which show that more and more minorities are being afflicted as well as the heterosexual community now has come into play, we then realize that, in the city of Houston, this is not just a homosexual disease afflicting our city but also that it is expanded, that while other States and other cities, and let's refine that to other cities, have higher percentages of minorities and heterosexuals afflicted with the disease that this city's homosexual population is more afflicted. Are we focusing, are we honing in on those specific problems, that specific problem?

Mr. HAUGHTON. Yes. In fact, I think we are focusing it to the extent that it is causing us some other problems. It is true that 94 percent of the cases in Houston are still gay and bisexual males. That has not changed since 1981 when the first cases of AIDS were reported in Houston, or at least were diagnosed in Houston. That has remained consistent over the 6 years. However, we are also aware of the possibility of that changing. And, so, in our educational activities, we have shifted gears from talking about risk groups to talking about high-risk behavior. Because everybody is vulnerable if they pursue certain high-risk behaviors. Now, the reason I say it is causing us a problem to identify and publicize this distribution is that just 3 weeks ago, our legislature voted down two very modest requests from our State health commissioner. He requested $1.2 million for services for the entire State of Texas with regard to AIDS and $675,000 for education for the entire State. Our legislature voted both of those requests down. I think they still believe that it is a gay disease. And I think that the data that we publish every month tends to reinforce that. The fact is that that is the way the picture looks.

Mr. LELAND. Is our city as ignorant as our State legislature?

Mr. HAUGHTON. No. Fortunately, our city is not. No. We have been allowed to, even though there are very few city funds that have been earmarked for AIDS, we have been allowed to use our resources to the maximum extent to put out the message about AIDS.

As a matter of fact, we have had a lot of help from the gay community, itself. The AIDS Foundation has done a terrific job of education in the gay community. And we use a surrogate set of statistics to show that.

Our department has been screening for sexually transmitted diseases in gay bars and gay bathhouses in this city for some 10 years. And we do that because contact tracing has never been very effective in the gay community. The names and addresses and telephone numbers we get never check out. And, so, what we do is, we in fact ask people where they had their contacts. And then we send teams of epidemiologists out into those communities to test for syphilis.

Up until 2½ years ago, we were finding 6 cases of syphilis for every hundred persons that we tested primary syphilis. In 2½ years, that has dropped to less than one per thousand. So, we believe that the gay community has done a good job of educating its own members.

Mr. LELAND. Now, Dr. Haughton, you have shown some invaluable—you have given us some invaluable statistics about our minority community and its affliction with the AIDS disease. Also, you obviously show some real concern about the proliferation of the problem within the heterosexual and minority communities.

Are we doing enough in the city? You said that the city of Houston has given some limited funds to this problem. Should the city of Houston allocate more funding for this problem not only to help with the problem in the homosexual community, but also in the heterosexual and, particularly, in the minority communities?

Mr. HAUGHTON. Well, I have about $100,000 of city funds earmarked for AIDS. But, as I said, we've been allowed the freedom to apply our resources as necessary to dealing with the problem to the limits that we can apply. You must remember that in the State of Texas, when there is a hospital district in a county, no other unit of government within that county can spend funds for medical care. And, so, as a health department and a city government, we are limited to preventive aspects of AIDS: education and testing and so on.

The question is: How much is enough? Our department took a 9.5 percent cut in our overall budget last year. I may have to take another cut going into 1988. So, to say that the city should spend more on AIDS, I would have to ask: Where will they take it from?

I would not like to see a repeat in Houston of what has happened at the Federal level. Most of the funds that the Federal Government has spent so far on AIDS education and risk reduction and so have been taken from other programs.

Mr. LELAND. Unfortunately, not from the Defense Department.

Mr. HAUGHTON. At the beginning that was true. It was taken from other programs.

I didn't hear what you said, Congressman.

Mr. LELAND. I just said, unfortunately, those funds that were taken from other places were not taken from the Defense Department. Of course we have a problem with crime here in the city of Houston. I certainly would not want to see us take those moneys from the Police Department. But I think that maybe because of the severity of the problem and I do not want to engage in any kind of controversial colloquy with you, Dr. Haughton, but I think that because of the rising problem in this country and the rising problem in this city, that we need to prioritize, if in fact we can, the problem of AIDS and more moneys being expended.

Mr. HAUGHTON. Now, let me make one point. I do not know if you have this set of slides in front of you.

Mr. LELAND. Yes, we do.

Mr. HAUGHTON. If you will look at the second page, you will see we have been tracking the rate of increase of AIDS cases in Houston. And if you will look at that chart, you will see that over the last 3 years, while the number of cases have been increasing, the rate of increase has changed and is trending downwards. We hope that that is a good sign.

Mr. LELAND. Very good.

Mr. HAUGHTON. You will notice that between 1983 and 1984, we had 126 percent increase in the number of new cases. Between 1984 and 1985, that dropped to 86 percent. And between 1985 and 1986, it dropped to 45 percent.

Mr. LELAND. But is that not misleading?

Mr. HAUGHTON. So, even though the numbers are increasing, they are increasing at a slower rate than they were 3 years ago.

Mr. LELAND. But is that not misleading to say they are increasing at a slower rate. If you take 50 percent of 10 as opposed to 25 percent of 500, the raw numbers are incredibly large in terms of the numbers of people increasing to be effective.

Mr. HAUGHTON. As I said, the numbers are increasing, but at a slower rate than they were before. Remember, about 2 years ago, they were predicting that the numbers would double every 6 months. That has not been true in Houston.

Mr. LELAND. Dr. Krim, does that give you much sense of relief?

Ms. KRIM. No. It does not give me much pleasure to hear that because the double of 1 is 2, but the double of 400 is 800, you know. So, less than double 400 is still more than 2.

Also, there is another thing that worries me is that in all this discussion, we always talk about cases of AIDS. As I explained, AIDS occurs years after infection occurs. And, biologically, the important event is acquisition of infection and we do not know where that is.

Mr. HAUGHTON. Well, one of the problems I have with the projections that are made is and I quote this from an article published by Dr. Jim Kern of CDC in November, I believe it is, of 1986, in "Public Health Reports." Their empirical model assumes that everything will continue as is and that any educational efforts we make will make no difference. That is not the case. And, so, while the number is growing, we must keep up some perspective.

If we believe in health education and if we are going to spend a lot of money in health education, then we must take into account what we believe that education will do in making these projections.

You know, these projections have a double-edged, a two-edged sword. For example, just recently, in this city, because of our concern about spreading in the heterosexual community, we began to emphasize education in that area. The result was that for people at risk, they were demanding more funds for education against AIDS. For those people who believe it is the punishment of God, they were saying, "Let's lock up all the homosexuals." So, we have to be careful about our education and the outcome of what we say.

Mr. Waxman. Well, it doesn't look like your State legislature has learned the lesson of this epidemic.

Mr. Haughton. I think they are in our second group.

Mr. Waxman. Well, the fact of the matter is, from what I hear you testifying, if you are spending $100,000 and that is it in the city of Houston, that is not an incredible expenditure for education.

Mr. Haughton. That is correct.

Mr. Waxman. And if your State legislature refuses to spend more money, then it seems to me they fall into that group that you have described where, unfortunately, the population will have to learn the hard way, after this disease spreads into larger numbers of people, before they take action.

But we talk about funds for this effort. What about funds for treating the patients with AIDS? Are your public hospitals not overwhelmed with the cost of treating these patients?

Mr. Haughton. No. That has not been a major problem in Houston. The hospital district is the agency responsible for health care for the needy. And, of course, that is where people fall after they have exhausted their other resources. That agency has a tax base of 100 mils. I think in last year's budget, they allotted about 22 mils. So, they have some freedom. Now, I must say, in their behalf, that they have been very sensitive to this problem. They have responded when M. D. Anderson, our cancer institute, decided not to treat AIDS cases anymore, they created an in-patient unit and an out-patient unit at Jeff Davis Hospital.

More recently, when the Institute for Immunological Disorders decided that they could no longer provide indigent care to AIDS patients, the hospital district doubled the size of their AIDS in-patient unit, and are now about to create a 20-bed hospice for those patients who do not need acute hospital care. They are very responsive.

Mr. Waxman. Maybe you are not the one to ask this question, but do you know the statistics of how many patients have health insurance to pay their bills, how many are on Medicaid, and how many have no source of payment?

Mr. Haughton. No, I do not. But I do know that most of the patients with AIDS in Houston have started out their problem at a time when they did have resources. The problem is on the far end: After they have had several hospitalizations, have been ill for a long time, have exhausted their insurance benefits, are no longer employed. Then is when the problem begins.

Mr. Waxman. Far end is a year? Six months?

Mr. HAUGHTON. Most of our death rate is quite high in Houston, higher than the national average. About 65 percent. And most of our cases have been dead within 2 years.

Mr. WAXMAN. Thank you very much.

We are pleased that Congressman Fields has joined us. Congressman Fields, of course, is from the Houston area and a member of the Energy and Commerce Committee, as well as the Subcommittee on Health. Mr. Fields.

Mr. FIELDS. Thank you, Mr. Chairman. I want to apologize to you and my colleague, Congressman Leland. There is a press tour today of the Hardy Toll Road which is a major transportation link in northern Harris County, and I had to attend that this morning. And, also, I am going to have to be leaving in just a second to go introduce Secretary Don Hodel who is here for the Offshore Technology Conference and the World Petroleum Congress.

I would like to have my prepared statement entered for the record, if I could. I also want to say that AIDS is public health enemy No. 1. I have usually been considered conservative on fiscal matters. However, I think more money needs to be expended in AIDS-related research. I do not think that anyone should be considered conservative nor do I think anybody should be considered a liberal on this issue. I do not think people ought to be considered Republican. I do not think they ought to be considered Democrat. I think this is a problem that our Nation faces and I think we must come to grips with this problem as a Nation and dedicate ourselves to its resolution.

So, with those opening remarks, again, I apologize for coming in on the tail end, but I did have one or two questions, if I could.

Mr. WAXMAN. Sure. First of all without objection, your statement will be put in the record at the opening of the hearing. And I want to say personally that I welcome those remarks because we are facing a terrible national tragedy with this epidemic and it is an epidemic that knows no political boundaries or ideological views of the people affected. It is one that we all have to get together on, whatever our ideological views, to try to combat. And I thank you for those comments.

Mr. WAXMAN. Please go ahead with questions.

Mr. FIELDS. Dr. Haughton, just a couple of questions. And I, again, apologize for missing your testimony, but going back to education. It has been my experience just in talking with people in a general way, there is so much misinformation and misunderstanding about AIDS. What are you doing in regard to education? And I know you were talking just a moment ago about some of the money that is being expended. But is there any coordination with volunteer groups going out into communities and talking about, you know, this particular problem?

Mr. HAUGHTON. Yes. We have created a speaker's bureau jointly with the AIDS Foundation. And epidemiologists, physicians, nurses, health educators from that speaker's bureau are available to speak to any group that requests our assistance and we also solicit groups that we want to talk to. One of the most important things that has happened in Houston resulted from Dr. Koop's, the Surgeon General's statement with regard to the education of children about this problem. The Houston Independent School District got in touch with us as soon as Dr. Koop made that presentation and asked us to assist them in developing a program to reach their children.

Since then, we have trained all 200 of their principals. We have helped them, together with Texas Children's Hospital and the Institute for Immunological Disorders to create a 1-hour training film for their teachers. And we are now in the process of conducting seminars for groups of 20 to 30 of their teachers and school nurses. And they have begun three pilot projects in three middle schools in the city of Houston—Houston Independent School District to implement that program of teaching young people about family life, about the problems of AIDS and how to protect themselves.

Mr. FIELDS. Besides school groups, do you feel that there has been a response. Is there solicitation of you for your speakers to come out and provide better information for the communities?

Mr. HAUGHTON. Yes. We have had a large number of requests from, more recently, employee groups. Employers are asking us to come make presentations to a group of their employees. We spoke to the Marriott Hotel chain employees, to several banks, to the flood control district. So, we get a lot of such calls. A lot of congregations are calling us to speak to their church-related groups, both their young people groups as well as their full congregation.

So, the word is getting around. People, even though there is still some degree of denial, because of our numbers, it appears still that AIDS is a gay and bisexual disease in Houston. Ninety-four percent of our cases are still in that category. But I believe that the word is beginning to filter down to the rest of our community that we can no longer talk about high-risk groups. We must now begin to focus on certain types of behavior. Because, in pursuing those behaviors, anybody is vulnerable. And I think that word is getting around and we are beginning to get a spark of interest from others.

I mentioned before you came that NBC had this national program last night. We set up a phone bank here and had four epidemiologists available to answer calls. And, in 3 hours, we got only nine calls. I think that was because that program was on the wrong station.

Mr. FIELDS. Let me just ask one other question. I appreciate the Chairman's indulgence. You represent the city of Houston and you are talking about information and it seems that you are being fairly aggressive on this issue. What about areas within Harris County that are outside the jurisdictional boundaries of the city of Houston, the smaller cities? In my congressional district, cities like Baytown, Jacinto City, Galena Park and also in the unincorporated, you know who is working in those particular areas? And is there coordination with you and other people?

Mr. HAUGHTON. No. We have found very little interest in the problem from the other five counties in our Standard Metropolitan Statistical Area. And, as you may be aware, Congressman, those counties include Montgomery, Ft. Bend, Brazoria, Liberty and Waller. They have very small numbers of cases. In the 3½ years that I have been in Houston, I had one call from Montgomery County, about 1 year ago, asking me to send a speaker out. I had a call from the health director in that county asking me to send a speaker to speak to a community group that he had pulled together. That is the only contact that I have had from outside the city of Houston.

Mr. Fields. Sir, just in closing, you know, we as a Nation found a preventative cure for polio. We had a national resolve to put a person on the moon. And it seems that we need that same type of resolve in this particular situation.

Mr. Waxman. Thank you very much. We certainly do need a higher resolve to deal with all the ramifications of this AIDS epidemic. I want to thank the three of you for your presentation to us. We appreciate it very much. We look forward to discussing the issues further with you. Thank you.

I understand that we are going to have a microphone for the witnesses. It is being set up right now. So, we will wait a second before we call the next panel.

[Pause.]

I think we are ready now to start, again. For our next panel, I would like to ask the following people to come forward: Reverend William Lawson from the Wheeler Avenue Baptist Church; Mr. Jose Perez, Gay and Lesbian Hispanics Unidas, here in Houston; Ms. Sue Lovell, Board of Directors, AIDS Foundation, and Mr. Chris Kihnel, President of People with AIDS Coalition. If you would please come forward and take seats in this area with the microphones.

We want to welcome you to our hearing this morning. We are pleased that you are here. Your prepared statements will be part of the record in full. We would like to ask you, if you would, to summarize in no more than 5 minutes, and when the bell goes off, we would like you to conclude your statement at that point.

We would like to start with Reverend Lawson. As I understand, the way the—the one—there is only one microphone. And, so, after you have concluded, just pass it along and we will hear from the other witnesses. I understand some of the audience are having trouble with hearing the witnesses. So, if you will pass the mike, it will be helpful.

Reverend Lawson, pleased to welcome you.

STATEMENTS OF REVEREND WILLIAM LAWSON, WHEELER AVENUE BAPTIST CHURCH; JOSE PEREZ, GAY AND LESBIAN HISPANICS UNIDAS; SUE LOVELL, BOARD OF DIRECTORS, AIDS FOUNDATION; AND CHRIS KIHNEL, PRESIDENT, PEOPLE WITH AIDS COALITION

Mr. Lawson. Mr. Chairman, and to Congressmen Leland and Fields, I will probably be able to give you back part of this 5 minutes.

Mr. Waxman. Speak up. There we go.

Mr. Lawson. I am probably the only one of the experts who is totally inexpert. I am a pastor and do not have access to all of the statistics and all of the data that some of my honorable colleagues have.

Can you still not hear me? You law folks tell me that you have to eat mikes.

I think that it goes without saying that all of us are concerned about what is quite clearly an epidemic. I do not think that anybody has any question that that it is of somewhat disastrous proportions.

I, as a pastor, am doubly concerned. First, because as a Black man, my background is in Africa, from which much of the AIDS problem seems to have come. And, as a pastor, we are very much concerned about our mission in the field which is in Haiti, which is also a center of much of the AIDS problem right now.

Our concern about AIDS as it has an effect on minorities, Blacks and Hispanics, particularly, is one that says that there is, right now, still not enough concern being expressed and we are very grateful to this subcommittee for having this hearing and for giving an opportunity for the several perspectives that are being presented here.

But it seems to me that what we first have to realize is that we are still looking at AIDS far too negatively. We are thinking of it as something that does involve a certain kind of bad risk community. And, whether we limit it to gays and drug users or whether we think of some other high-risk groups, we have to realize that it is also now infecting people who are neither gays nor drug users. It is now even infecting babies. And it seems to me that anything that has over 1,000 cases in Houston is certainly in the nature of some kind of an epidemic.

And it bothers me that I hear the city of Houston and the State of Texas saying that it is something that we can simply throw $100,000 at. That is probably about the cost of one bus to run our streets. That does not do a whole lot for this kind of disease. And my concern is that many of the people who need the kind of education are not now getting it.

I listened to Dr. Haughton, just a few moments ago, saying that the city of Houston Public Health Department is doing a great deal in the area of AIDS education; but, as I deal with people in the ghetto, my feeling is that probably most of them would not go to the Public Health Department. And, so, it does not surprise me that there would be only nine phone calls that came in. When, on the other hand, they see something like the AIDS Foundation, which is a private group, that then rings a bell. And, so, they probably would be making contact with them.

I think that there needs to be, quite clearly, a real priority placed on some kind of education. And there needs to be, likewise, some priority on treatment. It is not true that Blacks and Hispanics and other groups within the poverty community can take care of all of the needs involved in either learning about or treating AIDS. And my hope is that there can be some kind of collusion between government and the private sector that can work this out.

I would certainly agree with Congressman Leland that if we need to trim from any place, we probably need to trim from the Pentagon enough money to deal with something that is killing our people at this high rate.

Some of the words that I have heard is that, while we may have about 14,000 AIDS cases, we have go something like a million people who have been actually infected with that disease, but are not considered confirmed AIDS cases. I do not know whether those figures are right or wrong, but I know that even if they are not accurate, they are bad figures and something needs to be done about.

I am glad to see the Government now at least beginning to follow up on this. Congressman Leland knows very well, as one who is concerned about both health and hunger, that quite frequently those concerns begin with people like entertainers. And then, finally, the people who are supposed to be our elected leaders follow suit. So, I am glad to see the Government at least expressing some interest in this.

I am wondering if it is not possible to get the public school—and public school systems all have some kind of Federal funds—to recognize that this ought to be some kind of budget priority for them, serious budget priority for them. I am wondering whether or not we ought not to be able to convince the media, which has to be regulated by the Federal agency, that some of their public service time probably needs to be given to something else besides church programs. And I am glad about church programs, but I think that at least some of that public service time needs to be mandated for some way of getting to people who otherwise would not call up about AIDS.

My hope is that there can be an aggressive program involving Federal money, State money, local money and private money. And I think that at this point, the governments also have some kind, some kind of leverage on those companies that have Federal contracts.

I think that there are ways, at least of getting people involved. And my hope is that there can be the kind of involvement that can say, "We think that AIDS is a serious problem. It is a serious problem enough so that we can spend some concern and some dollars on it."

I wish that I could say something that would be a lot more scholarly about it, but I think that you have a lot of scholarship. Mine is just the concern of a Black man and a pastor.

Mr. WAXMAN. Thank you very much.

Let me suggest to the audience that it would be, I think, preferable not to applaud. I think it takes away from some of the demeanor of the hearing and, then, if you applaud when you like a statement. Then, there is an inclination to boo when you do not. And then it gets to be more of a circus than a congressional hearing. But I, if I thought we ought to applaud at a hearing, I certainly would applaud that statement. It was an excellent one. Thank you very much, Reverend Lawson.

I would like to now call on Mr. Perez.

STATEMENT OF JOSE PEREZ

Mr. PEREZ. Yes. I am from the Gay and Lesbian Hispanics Unidas.

Mr. WAXMAN. Could you speak up?

Mr. PEREZ. Sure. I am from the Gay and Lesbian Hispanics Unidas. And we began our AIDS education, Latina Community Prevention and Awareness Program, last year, with the AIDS Foundation of Houston. And one of the things that we found was that nobody knows anything about AIDS in this Latino community.

We did a resource guide that we took into the community. We had it published in one of the major publications, "Y Por Nation." And what we got was a series of phone calls that was really disturbing. One was from a non-English speaking mother of three who was worried about her husband's drug—IV drug abuse. All we could do was refer her to the Montrose Clinic. And then she said she could not talk to anyone at the Foundation. But she finally found someone to talk to. She was scared for herself and for her children. I mean she just had no idea of what was involved with this.

A mono-lingual, Spanish-speaking homosexual male feared that a health problem he was having had to do with AIDS. And he was not sure and he could not find anywhere to go to find out if it was or not.

A mono-lingual mother worried about her husband's extra-marital affairs, which she suspected included men. This woman was extremely upset. She was frightened and worried that her condition might be having an adverse effect on her children. And, again, no counseling. No anything for this group of people.

A non-English speaking Chicano, unmarried and childless, living with a middle-aged Black male, both of whom are IV drug users, is also worried about AIDS. She is worried because she does not quite understand the problem and she suspects that something is wrong with her own body. We informed her about the hours of the Montrose Clinic and referred her there.

This is just a sample of the calls that we have received in the wake of the publication of the resource guide. These Latinos have called us because we are the only available Hispanic-based organization doing anything about AIDS prevention and awareness in this city.

The resource guide and the workshop were completely funded by GLHU event held during New Year's Eve, which just raised a little over $400. What these projects did uncover was the ignorance and lack of material about AIDS which has gone into the Latino community here. It is an injustice to keep the Latino community in the dark about this disease.

It is as if we do not exist. This is a sophisticated form of racism. Not giving minorities the chance and the efforts of AIDS prevention is an insidious form of racism which is the most difficult to confront.

Latinos need a mass media campaign about AIDS prevention and awareness. The media campaign must be in Spanish to insure that it reaches every facet of the Latino community, especially the parents of Latinos, who, according to most demographic studies, are most comfortable with Spanish language material.

The need for minority based agencies to do the actual work of minority AIDS education is crucial. The existing AIDS service providers are structured to meet the needs of the white, gay males. Latino PWA's, on the other hand, are made up of a more diverse group of people, including women and children. All AIDS services for minorities must be upscaled because of the shorter life span of minority PWA's, which, nationally, is 6 weeks for Latino PWA's, as opposed to 2 years for everyone else.

Counseling services are non-existent and essential to the psychological well-being of minorities. Counseling is needed to help minorities in dealing with the stigma surrounding the common forms of infection and the idea of death, which is so much a part of this disease.

That is basically it. Thank you.

Mr. WAXMAN. Thank you very much for your testimony.

Ms. Sue Lovell.

STATEMENT OF SUE LOVELL

Ms. LOVELL. Chairman Waxman, Congressman Leland, Fields, I welcome you to—back to Houston. It is nice to have you here.

My name is Sue Lovell. I am a board member of the Texas Human Rights Foundation, a member of the Commissioner's State Health Task Force on AIDS, and a member of the AIDS Foundation, Houston, for the past 5 years.

As I said, I am glad to see you here today because, quite truthfully, we need your help. The AIDS Foundation is the primary mainstream AIDS service provider in the city of Houston, the fourth most impacted city in the United States with AIDS cases.

I would like, at this time, just briefly to recognize two other service providers in the audience: Eleanor Munger, who started Omega House, which is a hospice where people can go and die with dignity. And Sister Patricia, who is—started the Children's Home, which is a home where children that have no where to go, with AIDS can live. They share the same common goals and frustrations that we do at the AIDS Foundation.

I gave a lot of thought, today, to what I wanted to say to you. I would like to be able to say that the AIDS Foundation is doing an excellent job; but I cannot. We are doing the best job we can with the resources available.

Since the AIDS Foundation was started in 1981, our two main purposes were to provide social services for people with AIDS and education. Our social services program currently serves 400 clients. Our program includes a buddy system, transportation assistance, rent subsidies, a hospital helper team, Stone Soup, our food bank, and Macadory House, a home for indigent PWA's, which is now at full capacity—excuse me. Which is at full capacity and recently had to turn away two people that needed assistance in housing.

We currently have 72 new clients that are waiting intake to become clients of the Foundation. We have one paid staff member that oversees this whole program.

Our education program consists of a hot line, a speaker's bureau, which we are the ones that receives the calls to go to Baytown and Waller and League City, and all the other outlying areas. We have done workshops. We have seven different brochures. We were the first foundation in the United States to start a safe sex risk reduction program. In the past year, we have hired a minority educator, with funding made available from grants through the U.S. Conference of Mayors and the Chicago Resource Center.

I could go into greater detail about our education efforts and would like to do so because everybody likes to boast about your accomplishments. But I would be missing a very important point.

We cannot do the massive education that has to be done in this city because of lack of money. The most important message that we need to convey to people is: AIDS is preventable. But the type of partnership that is required to prevent the spread of AIDS is not happening in Houston nor in Texas. That is between the private sector and the Government.

Two days after Surgeon General Coop addressed a joint session of the Texas Legislature, the House Appropriations Committee voted to allocate not one cent to AIDS education, nor to the State Health Department's request for their AIDS program.

The city of Houston has spent only $21,000 on education between October of 1984 and the present on education. The county which provides hospital care and social services will be over-burdened if the predictions come true of 9,000 cases in Harris County by 1991.

I listened to Dr. Haughton this morning, and, in my heart, I would really like to believe what he is saying. But, in my head, I know it is not true. We, in Houston, cannot think that we will avoid the cases into the heterosexual population, the minority communities, the women, and the cases in children that other cities have experienced.

It would be a miracle if that happened, but; unfortunately, miracles do not happen in Houston, TX.

We, at the Foundation, have understood and have been concerned about the effect of AIDS on minority women and children. We know that it will take a targeted, educational program to reach Blacks, Hispanics, Asians, women; and, in truth, every person in Houston. But, again, this takes funding.

What we need is your help. Today, not one Federal dollar has come to Houston for education or patient care. That same effort that is given to securing funding for NASA or the same planning that goes into bringing a superconductor to Texas is needed on the AIDS crisis in Texas.

We will provide the expertise, the knowledge, the energy, the work, the volunteers, of which, we have 500 at our Foundation, in help preventing this disease and caring for people with AIDS, if you will provide us in Texas with the money that we sorely need.

You, the Federal Government, are our only help at this point. The funding is not going to be made available from the State, city or county. We will continue to raise money from the private sector; but we realize these dollars are limited, especially given the state of economy in Houston.

Without your assistance, women, children, minorities will unfortunately experience the same pain and suffering and loss that we have felt in the gay community I can tell you from a very personal standpoint: I do not want that to happen. Thank you.

Mr. WAXMAN. Thank you very much.

Mr. Kihnel.

STATEMENT OF CHRIS KIHNEL

Mr. KIHNEL. Distinguished Congressmen Leland, Fields, Chairman Waxman, thank you for having me. If I had known the context of Dr. Haughton's testimony today, as a Texan, I would have worn my boots.

My name is Chris Kihnel and I am a 30 year-old native Houstonian and Texan, and I am a person with AIDS. I am president of the People with AIDS Coalition of Houston, operating under the auspice of the National Association of People with AIDS in Washington, DC.

I was diagnosed with pneumocystis pneumonia on August 1, 1986. After three bouts of PCP, which nearly killed me, I recovered under the care of Dr. Gary Brewden and the staff of the Institute for Immunological Disorders. I was fortunate in having converted my group health insurance policy to a personal policy 3 months prior to my diagnosis after a job layoff. My policy covers everything but out-patient prescription drugs, including AZT, which has sustained my life up until now.

I must find the means to pay for this drug after 2 more weeks' grace period, since the open drug study has ended and AZT has been approved by the FDA, and there is no local, count, State, or Federal funding yet for indigents on AZT.

My only source of income is $627 per month Social Security Disability, out of which approximately $200 goes to my insurance coverage. Due to my qualifications and my concerns as a person with AIDS, I would like to address the concerns of AIDS in our Black and Hispanic communities.

According to national statistics, minorities take up 41 percent of the 33,000 confirmed cases of AIDS since 1981. Blacks and Hispanics are over-represented in AIDS cases. Blacks account for 12 percent of the U. S. population and 25 percent of AIDS cases. Hispanics make up 10 percent of the U. S. population and account for 14 percent of the total AIDS cases. Three out of every five children with AIDS are Black.

Based on future predictions, the minority community will continue to pay a heavy toll due to AIDS. Minorities in Houston in Harris County are imminently affected by AIDS and will continue to be affected in increasing numbers in the future.

Of particular concern is Black and Hispanic youth in Houston, among many of whom sexual experimentation, IV drug use, the use and abuse of tattoo needles, chemical inhalants and others. As the numbers increase, so will these and many other problems.

Great attention—local and national—has been directed on Houston in Harris County and its proposed solution to the management of the current AIDS problem as it effects indigents.

Considering the number of Blacks and Hispanics who depend upon public hospital and medical care, the facts regarding minority groups require an even heightened awareness by Harris County. Currently, poor people with AIDS are provided treatment through the Harris County Hospital District at Jeff Davis Hospital and its 16-bed AIDS facility.

There are current problems at JD's AIDS ward, including patients having been turned away because they have been told JD is at capacity, inadequate social worker staff, inadequate equipment, insufficient bilingual staff to service the AIDS area. Discharges are not coordinated between social work, medical and pharmacy. Often, family members have had to wait excessive hours due to this breakdown.

The status of continued County funding for AZT and other such life-sustaining drugs is yet undetermined.

Houston has a worldwide reputation as a medical center. The public health care system in this part of the country is more like Harris County's than systems in New York and California. The inquiring eyes of the media are focused on how we in Harris County in Texas will mobilize to respond to these urgent needs.

I know Mr. Waxman is concerned for my needs as he is for his own constituents in California. I met him in California. I hope Mr. Leland and Mr. Fields will follow his example and go back to Washington with the same compassion and dedication as my friend, Henry Waxman. Thank you.

Mr. Waxman. Well, thank you very much for those generous words. And you can be assured by the fact that Mr. Leland and Mr. Fields are here that they, and that I am here as well—we want to learn what we can from the experiences here in Houston and give this information to our colleagues as we try to figure out the appropriate Federal response.

Let me ask you this question. You have insurance. You are working with other people who have AIDS. Are they as fortunate as you are to have insurance?

Mr. Kihnel. No, sir. I would say over half the people I know, or possibly as high as 75 percent of them, are indigents and do not have insurance.

Mr. Waxman. Now, if they do not have insurance, how do they get their health care for AIDS?

Mr. Kihnel. Well, currently, through the Harris County Hospital District at J. D. Hospital—Jeff Davis Hospital.

Mr. Waxman. And is that—does that provide the whole range of services that are needed for these patients?

Mr. Kihnel. Although the staff out there has done an exceptional job with what they have to deal with, the quality of care is pretty good. I have some friends that go out there. I do not personally. I have some friends that go out there. And the quality of care is good at this time. But, of course, by the end of 1991, they will not be equipped to deal with the statistics—the number of cases.

Mr. Waxman. Now, you have insurance, but you indicated your insurance will not pay for high-priced prescription drugs. Will they pay for any prescription drugs?

Mr. Kihnel. They will only pay for in-patient prescriptions.

Mr. Waxman. In-patient.

Mr. Kihnel. And, since I am healthy and my life is being sustained by AZT, AZT and all my other out-patient prescription drugs are not covered under my insurance.

Mr. Waxman. Now, let us say you were on Medicaid, which is the health care delivery system for the people who have impoverished themselves——

Mr. Kihnel. Yes, sir.

Mr. Waxman. Would, would the Medicaid program in Texas pay for AZT?

Mr. Kihnel. No, sir, I do not believe so at this time.

Mr. Waxman. So, we are talking about a drug that means that people can survive——

Mr. Kihnel. Yes, sir.

Mr. Waxman. —with this disease. And often survive outside of the hospital setting. And without this drug, people will die.

Mr. Kihnel. That is correct.

Mr. Waxman. And, in Texas, under the Medicaid program, they are not paying for this drug. What happens to those people who do not have the drug paid for by the Medicaid program?

Mr. Kihnel. They will die.

Mr. Waxman. They will die; no choice about it.

Mr. Kihnel. Yes, sir. And, even though I have insurance and do not qualify for Medicaid because my—supposedly, my Social Security income is so high at $627 a month, since my insurance does not cover it, I am considered indigent in that case, too.

Mr. Waxman. Ms. Lovell, your Foundation is dealing with people who come in for services. I assume that most of the services that the Foundation and the AIDS Clinic supply are to gay men. Is that correct?

Mr. Kihnel. I would say a majority, but not all.

Mr. Waxman. You also provide services to heterosexuals?

Mr. Kihnel. Oh, yes, sir.

Mr. Waxman. Are people afraid to be seen going into what they might consider a gay clinic or a gay facility?

Mr. Kihnel. I believe that is true. We get a lot of calls on the hot line, in fact. Probably over 50 percent of our hot line calls are from people, heterosexual people, that want information, but are afraid to go anywhere and get that information, so call on the hot line.

Mr. Waxman. If someone wanted to be tested to see if they had the virus in their blood, in Houston, TX, where would they go?

Mr. Kihnel. They would go to the Montrose Clinic. The other—the program at the Montrose Clinic is voluntary, anonymous testing with pre- and post-test counseling. They have an excellent program. You may go to the Institute and be tested, of which there is a charge. But you are given the opportunity to pick either anonymous or confidential, of which "confidential" means a name is taken. We have a hard time in referring people out there other than saying, "Take it anonymously," because we all know the type of discrimination that takes place when your name is attached to an HIV antibody positive test: You can lose your insurance; you can lose your job. So, we inform people, if they want to take the test, to please take it anonymously.

Mr. Waxman. And do you know if there is a waiting period of time for people to get the test if they wanted to take it?

Mr. Kihnel. I do not know at the Clinic if there is a waiting time, truthfully. I have not heard that there is. I know that there was an increase in the request for testing.

Mr. Waxman. Mr. Perez, you think that we need a targeted campaign of AIDS education to reach the Hispanic community?

Mr. Perez. Yes. All Hispanics. Maybe one to even reach the gay Latino. And, you know, the Hispanic Community. Because there is none at the moment. People are scared out there. They are frightened, you know. They do not—they get a lot of misinformation. The Latino publications which exists here in Houston are over-wrought with misinformation about AIDS. And they continue this, you know, problem.

Mr. WAXMAN. Well, is it that they get misinformation and they do not think it could effect them because they think it is only a gay disease? Or are they getting misinformation about how it is transmitted?

Mr. PEREZ. I think what it is, is that the publications in most of the Hispanic communities is not taking it serious at the moment. There is not enough energy being put into it and that is one reason I am here. I am not a professional educator. I am not a counselor. I am just an activist and a concerned citizen. And we have had to take these initiatives to educate the gay Latino and Hispanic community, in general, because of that. We do not have the professionals out there to do that. What we have had has been limited.

Mr. WAXMAN. All right. I thank the three of you and Reverend Lawson for his testimony. It is clear that what is going on in Houston is not all that unique, except this city, Los Angeles, San Francisco, New York, Miami, are cities that are on the cutting edge of this epidemic. And the rest of the country will learn from your experiences and, hopefully, not from your mistakes. But, if need be, they will have to learn from mistakes.

And one mistake is that if we do not educate people, inform them, about what is happening with the spread of this disease, the numbers of cases are going to multiply. And, with those people who have AIDS, we have to make sure that they get the treatment necessary.

As a humane society, with the values that we hold, it is inconceivable to me that we would allow people to go without the one drug that could keep them alive. And, if we do that, then we are giving a lie to the values that we have claimed as a society, that we are not going to say to someone simply because they cannot afford health care that they are going to be condemned to death.

I appreciate what you have had to tell us today. I am going to turn over the question to Congressman Leland, and the gavel. Unfortunately, I have to leave to catch a plane: but Mr. Leland is going to chair the rest of the hearing, and we will share the transcript of comments with our colleagues in Washington and be mindful of what is going on here in Houston as we try to figure out what is the appropriate Federal response. Thank you very much. Mr. Leland.

Mr. LELAND. Thank you, Mr. Chairman. If I may, having assumed the position as Chair, now, dispense with the policy that has been established earlier, just temporarily. I would like for you to give your thanks to Henry Waxman, our Chairman. Thank you, Mr. Chairman.

I am particularly concerned about the information that was given by Dr. Haughton. I hope he is still here. But I am concerned about the political implications here. While I recognize Dr. Haughton as having spoken, not necessarily from his personal point of view, but from his representation of the city—I am concerned that, indeed, that if the city is taking an attitude that they are not prioritizing this in the highest way, not only the current situation with the AIDS epidemic in Houston, but the spreading of AIDS to all of our community will continue to increase in severity. I would like to just ask you to respond, if you will, more in full, about the implications here: The fact that the, if Ms. Lovell's statement is correct, Houston has only spent $21,000 in this matter, and reducing, I guess, to some extent, their commitment by $100,000 if in fact that is the case, where they have received $100,000 from outside sources.

What is your opinion about this in each of your cases, particularly, the gentleman who has AIDS now?

Mr. KIHNEL. Well, Mr. Leland, I think that due to the lack of the city, county and State in funding education that there is a great deal of ignorance and fear. And I believe most of the heterosexual community does not understand AIDS. They do not feel that it can effect them because of the lack of money that is being spent.

And I feel that the city of Houston has completely turned its back on its community as far as addressing AIDS and educating its community.

Mr. LELAND. Can you speak more specifically about the city of Houston and why you feel that it has not responded to the extent that it should?

Mr. KIHNEL. I think Sue could probably be more specific. All I know is that they have not spent anything on educating the community. And that has led to ignorance and fear.

Mr. LELAND. But it seems to me, though, that, if it is a matter of fear, that—and I guess it is more because of the ignorance—that, if it was a matter of fear, then indeed a lot of money would be spent.

Mr. KIHNEL. You would think so. You would think it would be one of the main issues on the city council's agenda; but, instead, they have ignored it.

Mr. LELAND. Ms. Lovell, would you like to respond?

Ms. LOVELL. Yes. I mean certainly the city has not paid the type of attention to this problem, nor is it a priority. That was verbalized today. Given the state of the economy in Texas and the financial problems that we are facing, you need to prioritize. There is money available through the Federal Government in which this city could go and secure to do the type of educational programs that need to be done.

Given the statistics in Houston, right now, of 95–96 percent of the cases still involve gay men, I believe that the general population is beginning to understand that this is not just a disease that affects gay men, but a disease which will infect them.

But I do not think they have quite gotten it, yet, and, especially, when they listen to statistics. What needs to take place is the leadership from this city needs to point out to the general population that, indeed, it is a problem for them. And that they need to be educated and, through education, they can prevent the spread of this disease.

Given those statistics that we have, we are in a unique position here in Texas to really show that education, indeed, can stop the spread of the disease. With the statistics of 95–96 percent, if we had a well-organized, well-funded educational program to the minority community—women, the general population, teenagers—we might be a model in showing that education does cut down the numbers. It is effective.

We have a particular difficulty with the Black community. It is perceived as a white person's disease. Unfortunately, we have leaders like Reverend Lawson that are standing up and speaking out.

But one person cannot do it alone. It will take a community effort from the Black community. It will take targeted, specialized programs into those communities, not just a general informational brochure.

The Hispanic community faces particular problems simply because of a language barrier, different cultural problems. And, quite truthfully, the influence of the church—that will make it particularly difficult in educating and getting them to understand that this can effect them, but they can prevent it from happening.

Women need to take it seriously. Especially, we have seen the numbers effecting women of child-bearing age. I take that, you know, quite seriously. And so should everyone.

So, quite frankly, the leadership in this city needs to stand up and say, "This is a problem. And we are going to do something about it. And so are you. And we are going to show you how to prevent yourselves from getting that disease."

If that happened, we might withstand those statistics that Dr. Haughton would like to have.

Mr. LELAND. I understand. Let me, before you pass the microphone, let me ask you: Were you involved in the testimony at all before the State legislature in an effort to try to get legislation passed where more funds would be or funds would be allocated by the State of Texas targeting this problem for resolution?

Ms. LOVELL. Yes, sir. I was involved with that.

Mr. LELAND. What was the prevailing attitude that you confronted with the State legislature in this matter?

Ms. LOVELL. I think the prevailing attitude was the getting caught up on the statistics, again, of 95–96 percent gay men and IV drug users. And it seemed to be a real lack of concern simply because IV drug use is illegal. And, in the State of Texas, we do have a sodomy law. So, it was like, "We cannot justify giving this amount of money in hard times to two groups of people which are really considered criminals."

I do not think that they understood that this disease isn't just limited to that group and we are very concerned about this ticking time bomb.

Mr. LELAND. If I may, and it might be conjecture on my part, but having served in the body of the State legislature for 6 years, it seems to me that by now—and I have been out of that body for now 9 years—that it would have evolved to contemporary times in 1987 when, in fact, our legislators should realize that even if those who are affected by this terrible, terrible disease are, as far as they perceive, undesirable, that in fact they should know that an epidemic of this kind is pervasive and, thus, affects the universal population of our city—our State, rather.

I just find—I find it very difficult to understand their non-response to this very serious problem.

Ms. LOVELL. So do we.

Mr. KIHNEL. So do we.

Ms. LOVELL. Yes. This is kind of where a trickle down theory comes into effect and is very effective. Obviously, there is homophobia in the Texas House. Because of that there is no money allocated, which means that because of homophobia, people—minorities, women, children—also suffer. So, it trickles down from homophobia and then because of homophobia, it really cuts off the care and help that other groups of people need. And that is really unfortunate. But they are not past that, yet, unfortunately.

Mr. LELAND. Mr. Perez.

Mr. PEREZ. Well, I would just like to comment on Dr. Haughton's remarks about having done some considerable work into the city of Houston regarding AIDS. All the past 2 weeks we have looked for materials on AIDS, pamphlets and other documents in Spanish, and it is almost non-existent. I think the only pamphlets I have seen are the Foundation—the AIDS Foundation's, here in Houston, that have published their, I think three of the Spanish language pamphlets. The city of Houston has not provided anything. I have not seen anything anywhere in any of the multi-service, purpose-service centers or any of the other city facilities. There just has not been any real effort from the city. And I do not believe there will be unless they are really nudged into it.

Mr. LELAND. Well, let me just thank all three of you for your participation and for the record, Reverend Lawson, for his participation, also. You have been invaluable to the Congress of the United States. And let me assure you that your testimony will be very highly regarded. And, for the purpose of the record, too, I would like to insert into the record, without objection, an article that is dated March 1987, that was written by Miss Allison Cook, I think her name is, in "Texas Monthly Magazine" dated March 1987. I think it corroborates to some extent what has been said here with this panel.

[The material referred to follows:]

REPORTER

BY ALISON COOK

Politics and disarray in Houston's public sector have left AIDS sufferers ignored or forgotten.

NO AID FOR AIDS

If Houston once had the political resources and the medical facilities to contain the spread of AIDS better than any other Texas city—a mayor sympathetic to the needs of her gay constituents, a world-class medical research community, and the only hospital in the country devoted exclusively to AIDS—it clearly missed its chance to do so. With 1027 cases reported so far, Harris County has the highest number of cases in the state and the fourth-largest number in the country. Yet little has been done by the public sector since the epidemic appeared in the early eighties, and fundraisers estimate that Houston is running four years behind other big cities in informing the public and protecting it from the spread of the disease. Chicago, which ranks eighth in the nation, spends $250,000 on AIDS education, while the $84,253 that Houston spends goes not to prevention but to epidemiology—tracking the disease. Houston's organizational and educational efforts pale beside those of Dallas, which has 533 cases, slightly more than half the number in Houston. The situation is all the more dire because state funding for AIDS education is unlikely. Shortly after U.S. surgeon general C. Everett Koop went before the Texas Legislature and predicted a ninefold increase in the disease by 1991, a House committee turned down a request for more AIDS funding.

Certainly part of the problem lies in Houston's economic malaise and its long-standing commitment to a low tax–low service ethic, never much help when it comes to health care. But many fundraisers see the problem as political—specifically, the love fest that once existed between Mayor Kathy Whitmire and her gay constituency is souring. The falling-out stems from the 1985 citywide referendum to prohibit discrimination against homosexuals in city government, the Welch-Whitmire mayor's race, and a threat by factions in the gay community to sabotage the city's campaign

A BOY'S GOTTA EAT

Galveston heir Shearn Moody's indulgent entertainment at his seaside ranch was once the stuff of island legend. So it's nice to note that amid his recent legal entanglements—stemming from his collapsed insurance empire and some questionable grants from his family's Moody Foundation—Shearn still finds time for a bit of nightlife. Galvestonians report frequent Shearn sightings in the dinner line at the local Wyatt Cafeteria.

ILLUSTRATION BY REAGAN DUNNICK

to get the national Democratic convention unless more money was allocated for AIDS. The result: a perception among gay leadership that the city has abdicated its responsibility for this particular health care crisis. "Houston as a political entity hasn't responded the way it should," says Don Elgin of the Montrose Counseling Center.

In this instance, Houston could have used more of Dallas' can-do spirit. Because Dallas lacks Houston's enormous medical resources, it was quicker to perceive the devastation that AIDS could wreak on its public health system. Though gays initiated AIDS awareness programs, the public sector backed their efforts. Preventing the spread of the disease was frequently framed as a dollars-and-cents – as opposed to gay – issue. In Houston the majority of early fundraising and education was done by the privately funded AIDS Foundation. All along, there has been the usual buck-passing between the city and county governments. At a time when Koop and state health director Robert Bernstein are urging community leaders to confront the magnitude of the crisis, Houston health director James Haughton is downplaying the problem, comparing AIDS with such noncommunicable illnesses as breast cancer – a disease for which the city already has educational programs. When Haughton did try to include facts about AIDS with city water bills, the effort was squelched from above. Though Whitmire has established a task force on AIDS, it is viewed as ineffective: it has no budget, no authority, and no coordinating powers; it has produced no educational materials, nor has it raised any money.

The lack of coordination between the public and the private sectors as well as among public health agencies hurt Houston in a big way last year, when the Robert Wood Johnson Foundation wanted to donate $17 million to ten communities to coordinate all local service agencies to assist AIDS patients. Houston lost out, while Dallas, which had the backing of city health leaders and one of its oldest community groups, got one of the grants. A factor in Houston's loss of the money may have been that during an on-site visit by the foundation committee, the mayor didn't recognize the head of her own task force.

Houston's Institute for Immunological Disorders, the country's first AIDS hospital, has also suffered from little community support. Created by an unusual alliance between a nonprofit research institution – the University of Texas medical system – and a for-profit corporation called American Medical International (AMI), the institute soon found itself mired in financial problems. The reason: a shortage of paying patients. The institute accepted the transfer of indigent AIDS patients from UT's M. D. Anderson Hospital and Tumor Institute and was quickly swamped by the huge patient load. After losing more than $2 million since opening last September, the institute recently closed its doors to indigents. Rivalry between the institute and other AMI hospitals with AIDS wards has further lessened its chances for survival: private doctors are loath to give up their patients – and their fees – to the staff of the research institution.

There are signs that Houston is trying to catch up. Councilman George Greanias has issued a proposal – the first by a public official – calling for expanded city funds for agency coordination and for education programs. Of particular concern are minority communities, the next place the disease is expected to spread. Still, progress is slow, and Houston has a long way to go. "AIDS is preventable. That's the one thing we have to remember," says the director of one fundraising organization. "We have taken the position in this country and certainly in this city that it's not."

Mimi Swartz

Mr. LELAND. I want to thank you very much.

Ms. LOVELL. Thank you.

Mr. LELAND. The Chair would now like to ask that Dr. Peter Mansell from the Institute for Immunological Disorders and Dr. Robert Awe, from Jefferson Davis Hospital, please come forward for your testimony.

Let me welcome both of you. Let me also apologize for the necessity for the Chairman to have left by this time. He assured me that he was as interested in your testimony as those who had appeared before you and, indeed, will look at your testimony, as a matter of record, when this record is completed. And for the purpose, too, of your testimony, the entirety of the testimony of the Subcommittee on Health and Environment of the Energy and Commerce Committee will also be made available. Your testimony will have been available to the membership therein and to those who are concerned about this very dire, dire problem.

Dr. Mansell, you may proceed.

STATEMENTS OF PETER MANSELL, INSTITUTE FOR IMMUNOLOGICAL DISORDERS; AND ROBERT J. AWE, CHIEF, PULMONARY MEDICINE, JEFFERSON DAVIS HOSPITAL

Mr. MANSELL. Congressman Leland, it is a pleasure to——

Mr. LELAND. You might want to hold it very close, Dr. Mansell.

Mr. MANSELL. There is a switch. If all else fails, follow the directions. I speak about as softly as you do. It is a pleasure to meet you, again.

I must admit that I sometimes wonder if I live in the same city as Dr. Haughton.

But without going into that in any greater detail, I must say that I find some of his wishes highly desirable, but some of the facts on which he appears to base them are rather questionable.

I do disagree with him intensely about his implication that M. D. Anderson, which is the State cancer center, abandoned AIDS patients. This, in fact, is not the case at all. And the Institute, in which I have the honor to work, is a marriage between American Medical International, a private hospital owned company, and the University of Texas and M. D. Anderson Hospital and Tumor Institute, which still employs me, I am glad to say.

I think that I would like by way of testimony to give a very brief outline of the history of the AIDS epidemic as I see it in Texas. We saw our first case at M. D. Anderson of a person with AIDS in November of 1981. And 2 months later opened a clinic at M. D. Anderson. And, in the course of the last 5 years, we have seen 1,400 referred people with AIDS or with AIDS-related diseases.

In September 1986, the clinical activity, I was moved to a new location, the Institute for Immunological Disorders. And we are currently seeing almost 400 new cases of people referred at that Institute and our current modus operandi philosophy of looking after people, as I think is becoming more common, is to put the great emphasis on out-patient care. We currently see over 1,000 out-patient visits a month and never have more than approximately 15 or, at most, 20 in-patients.

And this, I think, is important because of cost considerations on the one hand and also because of the dignity and the quality of care that can be given at home as opposed to in the hospital.

Very recently, to my great regret and that of my colleagues, too, AMI, that owns the physical facility, was forced to insist that we see no new unfunded patients. And the reason for that, I think, is important to point out that AMI has spent $2.5 million on unfunded, indigent care between the beginning of September 1986 and March 1987, without any help from Federal, State, county or city sources.

Now, I may—and, indeed, I do regret this necessity enormously and hope that it will only be temporary. But I think it points out the dire problem that we have in this country and in Texas.

In January of 1982, my colleague, Dr. Guy Newell and I rang the Texas Department of Health in Austin to tell them that we thought, given what little we knew about AIDS at that stage, that Texas was likely to have a serious problem in the future. And, now, Texas is the fourth State and Houston the fourth city with numbers of people with AIDS. And is still, so far as I am aware, apart from Dr. Bernstein's panel, which is a bright spot in an otherwise very murky situation, there really is no planning and no funding. And, indeed, there may actually be negative planning and negative funding, if that is something that one can think about.

What I think bothers me even more than that is that given what we know about the incubation period of this disease and the latency period, all those individuals—maybe 10,000 in Houston or in Texas who will be sick in 1991, are already infected by the virus. And we have so far no capability of caring or ameliorating the effects of that infection.

The necessity for education as a means for prevention is enormous. We have an educational activity at the Institute of which I am very proud. I was a founding board member of the AIDS foundation and was, at least in part, instrumental in helping some of the early and I think excellent educational programs that that organization began and continues.

Clearly, we need to educate people. Clearly, the heterosexual population and the teenage school population is of tremendous need of intelligent, factual, well-delivered, effective education. And, frankly, I do not see that happening, other than as a result of the city auspices, county auspices or State auspices.

Finally, a word about the problem that indigent patients have. In our clinic, when people came to the clinic at diagnosis, before we had to stop seeing unfunded patients, approximately 12 percent had no funding. The problem really is that as the disease progresses, as employment is lost, as insurance is lost, that percentage rises to well over 50 percent. And, unless something can be done to provide humane, effective, economic care for these people, I personally agree with the Hasting's Center report in October of last year which proposes that AIDS may be the one thing that drives this country's health care system into socialized medicine—a thing which I personally would applaud, but is regarded as heresy by a lot of my colleagues.

The program at the Institute for Immunological Disorders consists mainly in clinical research. We are attempting, as best we can, with an aid of a contract from the National Institute for Allergy and Infectious Diseases, to look for drugs other than, but common with, AZT, and other agents which I will not go into details, to try to prevent and to treat this disease.

We have an educational and a basic research arm. We have a prevention activity. We may, I hope, be one of the first, if not the first places to mount a trial of a vaccine against this virus. We have a screening clinic and we also have a hot line. And I hope very much that these activities can continue to help the people of Texas and surrounding States. Thank you.

Mr. LELAND. Dr. Awe.

STATEMENT OF ROBERT AWE

Mr. AWE. Thank you.

Human infection in the indigent minority and majority population of Houston, if current projections are correct, will soon raise the cost of care to these patients to a prohibitive level in this county.

At present, 20 to 30 percent of the medicine beds at Jefferson Davis Hospital are occupied by AIDS patients. About 30 to 40 percent of our AIDS patients are minorities. I have the strong impression that my Black and Hispanic patients are not as well-informed as are the whites about AIDS prevention and the resources available once they are diagnosed. More innovative education is needed to reach these groups.

Due to current Texas law, only a small minority of indigent patients can depend on State assistance to pay medical expenses. The public hospitals in counties lucky enough to have them must budget for this loss. Relief from the Texas legislature is a fantasy.

One and only one possibility exists that can currently stem this inevitable tide. And that is AZT. About 40 percent of AIDS patients at Jeff Davis, who are on AZT, are minorities. The cost of this drug is very high. And the taxpayers of the county currently are the only ones who are paying for it.

However, only three or four of the patients seen at Jeff Davis last year were born in this county, and only a handful of AIDS patients seen and paid for through the county facilities are from Texas. The medical staff at Jeff Davis is happy to take care of these patients. And we admire their struggle to fight against the impossible odds of this disease. But this fight is costly, both emotionally and financially.

I do not think that the city and county officials of the dozen or so of the major cities devastated by this epidemic should be asked to bear the cost, alone. The sons and daughters of small town America came to the big cities because they wanted a brighter life, less encumbered by small town prejudice. They came by the thousands and they have died by the thousands.

In their exuberance of freedom, they were struck down by a virus that no one knew existed. One to 2 million people in this country, we assume or think, are infected with this virus. How many of these will develop disease is uncertain; but it may be as high as 50 percent.

We have to stop it from spreading further. AIDS is a very simple disease not to get. But it is a very expensive disease to treat. AIDS is a national trauma and requires national mobilization and cooperation. Rapid Medicare funding of newly diagnosed patients is desperately needed. Better drugs than AZT are in sight. But, for now, assistance must be given to those who cannot afford to pay for it. Thank you.

[The prepared statement of Mr. Awe follows:]

Statement of Robert J. Awe

The problem of HIV infection among the minorities and medically indigent of Houston and Harris County, Texas, has not yet reached such proportions that it has overwhelmed the County Hospital District but if the current predictions of its increase are correct, it soon will.

At present, the pulmonary medicine floor at Jefferson Davis Hospital has 54 beds. Eight of the beds are in the AIDS Unit, but it is always full and usually four to eight more beds are utilized by AIDS patients. This is despite a short average length of stay for most patients and increased out-patient treatment for their opportunistic infections.

If this population of patients increases as projected, (estimated 10,000 cases in Harris County by 1991) the number of beds will have to increase considerably. Contingency plans are in place but will be extremely expensive.

In 1986, 146 AIDS patients were admitted to our hospital; 30 were black, 25 were Hispanic, and 91 were white. Clearly, AIDS is affecting the minority population as well as the white risk groups and an increased effort to reach the black and Hispanic populations with effective education is needed.

The average cost per patient day is $540 at Jefferson Davis Hospital. Only two of the 146 people admitted in 1986 were "paying patients" through Medicaid. Most of our patients have worked before they got sick. Thus they qualify for Social Security Disability and, in Texas if their Social Security Disability check is greater than $340 per month, the Medicaid is stopped which means they have no medical coverage. They will not qualify for Medicare until they have been disabled for 2 years and most will not live for that long.

One, and only one, possibility exists at present that may stem the inevitable tide of HIV infected patients progressing into AIDS. And this is Retrovir (AZT). Currently, 35 patients at Jefferson Davis are on this drug and the results are truly remarkable. Only three patients on AZT for greater than 6 weeks have had to be readmitted, and all were for short stays (less than 5 days). Of the 35 patients, 9 are black, 6 are Hispanic, and 20 are white.

The Harris County Hospital District has budgeted $500,000 to pay for AZT for next year because we projected about 50 patients would be on it by then. However, with the recent release of Retrovir (the new trade-name for AZT) to a larger population, it is probable that well over 100 patients with AIDS will be placed on this drug in the next 6 months, at a cost of over $1 million. Although it can be justified that it is cost-effective to spend $10,000 per year per patient to keep them relatively healthy and out of hospitals, it will still place an overwhelming burden on the taxpayers of this county.

I am afraid that many lower income patients who are now working but have inadequate insurance coverage will become medically indigent because of the high cost of AZT. They will come into the public hospital system to obtain this life-sustaining drug. I do not feel the local government of the major cities (New York, San Francisco, Los Angeles, Houston, etc.) should have the burden of this epidemic alone.

AIDS is a national problem. It requires national coordination and mobilization. I strongly urge that AIDS patients be eligible for Medicare soon after the diagnosis is made, and that the cost of AZT be covered, at least partly, under this program.

Mr. Leland. Does the Institute accept patients whose only source of payment is Medicaid?

Mr. Mansell. Yes.

Mr. Leland. Where do you refer patients without insurance?

Mr. Mansell. Well, apparently, there is only one place in this area that I am aware of. And that is Dr. Awe's clinic at Jefferson Davis. I think that people who have the ability to travel can go down to the John Sealy Hospital in Galveston, but that is a considerable way. And the facilities are limited there, as well.

Mr. LELAND. What percent of the Institute's beds are occupied on most days?

Mr. MANSELL. Well, we have the capability, currently, of looking at about 80—75 to 80 in-patients. We have never had more than about 20. And that is partly due to our philosophy, which is, as I pointed out, is to try to keep people out of the hospital in order to look after them, I think, better and more humanely and reduce costs.

Mr. LELAND. Does your Institute receive Federal or State assistance in providing care or in preforming research?

Mr. MANSELL. We have a contract from the National Institute of Allergy and Infectious Diseases which pays some salaries and some supplies for basic research and clinical research, but nothing related to patient care. We have managed to get funds, in some cases, from private pharmaceutical companies to cover some patient-related costs. But they barely or seldom cover anything other than sort of bare minimum costs.

Mr. LELAND. Let me ask Dr. Awe.

Dr. Awe, roughly, what proportion of your AIDS patients have insurance?

Mr. AWE. None of them. By definition, to come to the county hospital, they cannot have insurance.

Mr. LELAND. Are they Medicaid beneficiaries?

Mr. AWE. Well, see, that is the problem with Texas law. They—as soon as they are diagnosed as AIDS, they get on Medicaid. But, most of the AIDS patients have worked and have had jobs and have paid into Social Security. Within 5 months of being disabled, they then get their disability through the Federal Government and Medicaid is cut off. When they get their Social Security Disability, this does not cover hospital care, so, that only a very small number of so-called "patients"—our patients at Jeff Davis—pay. Even through Medicaid, it has been run out by then.

Mr. LELAND. In that light, they are related to the gentleman who spoke earlier who was or is an AIDS victim?

Mr. AWE. That is correct.

Mr. LELAND. Who pays for the care of people with no insurance or Medicaid?

Mr. AWE. The taxpayers of Harris County.

Mr. LELAND. To what extent is that allowed over a period of time?

Mr. AWE. I am sorry, I do not understand the question.

Mr. LELAND. Well, the question is: How long, how many of these—are all patients allowed to come in to the Harris County Hospital?

Mr. AWE. No, sir. They are not. There are very strict requirements to get indigent care in this county. Number 1, obviously, you have to be indigent. Number 2, you have to have been a resident of Harris County for at least 6 weeks. And you have to prove that.

And, so, what we have is problems with patients coming from surrounding counties with AIDS, who we cannot take care of unless they are, you know, literally at death's door, because they are not residents of Harris County.

And it is my understanding that John Sealy in Galveston will not take patients from most counties in Texas. They only take them from three or four of the surrounding counties of Galveston. So, it is a tremendous problem for patients coming from outside of Harris County to get care anywhere, particularly, if they are indigent.

Mr. LELAND. Will John Sealy take patients from Harris County?

Mr. AWE. No, sir. They will not.

Mr. LELAND. They will not. Then that goes right to the heart of the concern of my colleague, Mr. Fields, who was concerned about those outside of Harris County.

Mr. AWE. Absolutely.

Mr. LELAND. When——

Mr. AWE. I am sorry.

Mr. LELAND. No. I just wanted to find out where they go, then, if they cannot get help here in Harris County or in Galveston County?

Mr. AWE. Right now, I do not think there is any place they can go. I really do not. I think this is why it is so important that the Federal Government realize that this is a National problem. And the only solution that I know of is to get these folks on Medicare, which is Federally funded, as early as they can. Right now, they can get on Medicare if they have been disabled for 2 years. But, as you well know, most patients with AIDS do not survive 2 years. So, very rarely, do they live long enough to even get on it.

Mr. LELAND. So, then, there are people out there who are literally at the brink of death and some who have died because they do not have access to the kind of care that is provided through the county—through the Harris County Hospital District?

Mr. AWE. I am convinced that that is true, yes.

Mr. LELAND. What—maybe I should ask—well, before I ask this question of both of you, let me ask: Roughly, what percent of your hospital's—you said 20 to 30 percent; is that right? The Harris County Hospital District?

Mr. AWE. And that is just medicine beds, obviously. Jeff Davis is really, mainly, an OB hospital. It is the largest obstetric hospital in the whole country. But the seventh floor of Jeff Davis is a medicine—of course, it is part of the Baylor program: Baylor teaching hospital. And there is about 55 medicine beds. And about 20 percent of them all are usually occupied by AIDS patients.

Mr. LELAND. And what percent of them are minorities?

Mr. AWE. It runs around 30–40 percent are minorities. When I made rounds Saturday, there were 10 AIDS patients in the house. Eight were Black, one was Hispanic and one was white. But, again, that was an unusual weekend. But it usually runs more like 40 percent.

Mr. LELAND. About 40 percent.

Mr. AWE. Right.

Mr. LELAND. Let me ask you something. I hear the resounding cry for politicians who are in positions of authority to do something about this in the State, Federal and local governments. Let me just ask you: What is your admonition to us, those of us who have some ability to hopefully do something about this program?

Mr. **Awe**. Well, it just seems to me, as I said in my opening comment, that the cities—the big cities like Houston and San Francisco and New York and Los Angeles are having to pay exorbitant amounts of money to take care of these folks. And as I—we just are not going to have the money in Harris County. If it is true that we are going to have 10,000 people by 1991, we are going to have to open up huge numbers of new beds and hire new staff to take care of these folks. And it looks now like those predictions are going to be accurate. And we are going to have to go, I guess, to the county taxpayers and ask them for more property taxes.

But I do not think it is fair that Houston and the residents of Harris County have to pay all of this cost. I think this is a National, Federal problem.

Mr. **Leland**. Now, Dr. Awe, you are talking about—you are talking about patient care, now. And, on top of that, we are talking about preventive measures like education.

Mr. **Awe**. That is true.

Mr. **Leland**. We are talking about even a more massive amount of money.

Mr. **Awe**. That is true. It is very expensive, but it is something that has to be done. These people are dying and probably most of the ones that are infected are going to eventually get the disease. And, once they get the disease, they are very hard to take care of and it is very costly.

Mr. **Leland**. I am concerned that the State legislature has done what it has done. Do you think that this problem is priority enough to the extent that we ought to expect and hope that the Governor of the State of Texas will call a special session—it seems that since this session of the legislature is so far spent—targeting or at least prioritizing this issue as one that should be regarded as substantial enough for the Governor to pay that kind of attention?

Mr. **Awe**. Well, I do not know if I could recommend they have a special session. All I can say is: We went to them and asked them just to help us pay for AZT, which we estimate Harris County, alone, is going to cost $1 million in the next year, out of our local hospital budget just to support AZT for our indigent patients, which we, of course, intend to do. But, when we went there, they just said it is Houston's problem. It is not problem as far as Texas is concerned, not considering the fact that when Houston was the boom town, people came from all over the country to this city. And, now, many of them have AIDS.

Mr. **Leland**. Well, the last I looked, I did not realize that Houston had seceded from Texas.

Mr. **Awe**. That is what they said. They said, "It is Houston's problem. I will not fund this."

Mr. **Leland**. Well, let me ask you something, Dr. Awe. Have you appealed to the Harris County delegation to the State legislature, which at one point—at one time in history, was reputed to be the most powerful delegation in the State legislature.

Mr. **Awe**. We have written letters asking Mrs. Moore, who is the Administrator at Jeff Davis, went up there personally and testified, asking for help. And they, just, to say the least, were unsympathetic with our problems.

Mr. Leland. Well, may I suggest something to you. And I guess this is outside the purview of my responsibilities as a legislator in Washington, but I think it is my responsibility as an aspiring humanitarian, and that is that you might call on the Harris County delegation to the State legislature to do all that they can to rectify this horrible situation that has been imposed by the State legislature by its inaction.

Mr. Awe. Yes, sir. We will certainly try that.

Mr. Leland. Dr. Mansell, do you have any other comments you would like to make?

Mr. Mansell. Well, I think from the Federal point of view, setting aside more local considerations, one thing that is terribly important is that the decision of the high court last year somehow be set aside: that employers can fire employees whom they think pose a health threat to the rest of the work force. This has adversely affected people with AIDS to a tremendous extent.

Because, of course, what happens following that is these poor individuals lose their health insurance and even the provisions of the Cober Act are totally inadequate, since they usually cannot afford to pay their own health insurance.

I absolutely agree with everything that Dr. Awe said. I think that until the legislature and, perhaps most importantly of all, the people of Texas realize that this is a problem that affects everybody, regardless of race, color, creed, sexual preference, or anything else, we are really not going to get very far.

I had the good fortune to attend a breakfast at the Governor's House at which Surgeon General Koop was a guest. And I overheard a conversation from one of the Harris County legislators with him complaining about the fact that if money were given to solve the—as he put it, "AIDS problem," then money would have to be taken away from crippled children and our cancer patients. And how would one not be able to make the kind of choice that he was suggesting?

And I think that it is this attitude—more than anything else—which caused the disallowment or non-voting or negative legislature on the part of Austin on funds to help people with AIDS.

Mr. Leland. It looks like we have to begin our education program with our politicians.

Mr. Mansell. Are you going to open this to other people on the floor? Is that a question I can ask off the record or not?

Mr. Leland. Well, no. You are very welcome to ask any question of the Chair that you so desire. We have very serious time constraints. The recorder and the Chairman's assistant both have to get back to Washington, and, as an official hearing, we must adhere to the parameters that were set out prior to the hearing time.

Let me suggest to you that what I can do, as an adjunct to this hearing and I will plan to do that because I understand that there are many concerns here that we have not, in Houston, adequately covered this topic, that this Member of Congress, and hopefully with the concerns that Congressman Fields has represented here, today, we will further pursue this matter by having possibly a county-wide hearing, or even with the concerns that Representative Fields has with those who are outside the county, to whatever practical extent that we can, we will hold an informal hearing on this matter or hearings on this matter in order that we can get the full participation of those who would want to participate.

This is not just a "Show and Tell" one-time affair, as far as I am concerned. This is something that we are going to have to concern ourselves with over a long period of time. And this one Member of Congress, anyway, is committed to further pursuing this matter.

It has been over a year, now, that we have asked the Chair to come and participate in a hearing like this because of budget constraints. I might add that we were hit as hard—those of us who are Chairs of committees and subcommittee Chairs were hit as hard with the Gramm-Rudman perpetration, if you will, as anybody. And, because of that, we were unable to travel to do many of the field hearings that we wanted to do last year.

Things have loosened up to some extent and to that extent we want to pursue this matter further. We want to do some onsite visits, as well as holding further testimony and doing open forums so that we can get a greater participation. We apologize to those of you, by the way, in the audience who would want to participate at this hearing. But, hopefully, you will bear with us and understand that we are committed and that this is invaluable. This has been an invaluable hearing and hopefully it will illuminate the problem in the city of Houston to the extent that we will get some response for the powers that be.

With that, let me just thank the two witnesses who have appeared here. Let me thank all of you. Again thank Texas Southern University for hosting this, and more particularly, Gene Harrington, who has been most gracious in facilitating this opportunity for us, today.

Let me just say that some of the problems that we have incurred, too—also illuminate another problem. And that is that Texas Southern still remains, to some great extent, the bastard college of the college system of this State. And some of those problems that we have incurred today have been because of the lack of resources provided Texas Southern University.

And, as an alumnus of this very distinguished institution, let me say that I hope that in the future we will have this proportionately—especially regarding the past transgressions on the part of the State legislature—we will have proportionately the adequate funds to run this institution as a first-level institution in our State. The first level institution that indeed it is, at least in terms of the faculty and administration and the student body that matriculates here.

I thank all of you. The Congress will continue to monitor the situation and the Chairman, of course, is an outstanding leader in this area of concern and I associate myself to the extent that I am as committed to doing as much as I can as the Chairman is.

Let me also issue one more admonition. Since I am a Member of the United States Congress who has a parochial interest in the city of Houston in that I represent at least 525,000 citizens of the city of Houston, and that is that, while we do concern ourselves with the spreading problem of AIDS amongst the heterosexual and minority communities, that indeed we should not—just because that problem is spreading to other communities, we should not ignore the very serious humanitarian problem of ignoring the problems of the homosexual community of our city, or State and our country.

I think that we should have heeded the call a long time ago, regardless of the sexual preference of anybody who has been affected or afflicted by this incredible disease.

We represent a country that is based on the moral authority in the world that we hopefully assume. We recognize that there are many faults with our system. And we hope to correct them. But I think that first and foremost, when any segment of our human society is at risk, this country should indeed pursue trying to resolve those problems as quickly as possible and as effectively as possible.

So, with that, let me just thank all of you for your participation and hope that America will indeed become America for all of its people.

Thank you very much.

[Whereupon, at 11:55 a.m., the hearing was adjourned, to reconvene at the call of the Chair.]

[The following statement was submitted for the record:]

Statement of AIDS Foundation Houston by Michael B. Wilson, President Emeritus

Having AIDS anywhere is a physical, emotional, financial, and personal tragedy. Living with AIDS in Houston is punctuated by an apparent lack of concern, compassion, and response from those public and private agencies we expected to come forward with help.

Since 1982, we have knocked on every door at City Hall; we have been told repeatedly that such a health issue is not the responsibility of the city government. We have beaten the trail from health departments to health-related funding agencies; we have been told that AIDS was not a problem in Houston. We have prepared educational materials on AIDS prevention to be informed such efforts were lewd and disgusting. We have developed and offered training programs, brochures, and policy manuals for businesses, school districts, and public health agencies only to have them tabled by frightened administrators. In the vacuum, we developed our own social service, assistance, counseling, and educational programs to fill in the gaps. All were funded by the efforts of community volunteers.

Other than Federal social security and a few minimal county and State programs for the near-indigent, the prospects for a person with AIDS in Houston are bleak. I've heard it said, "If you're gonna get AIDS in Houston, you'd better be rich or well-insured."

For the Houston AIDS victim who has had insurance canceled, lost his job, or for whatever reason become indigent, there is precious little hope for medical care and treatment other than the strained resources of the county hospital district and the State cancer hospital.

And the list of special problem of living with AIDS in Houston goes on and on—from dealing with workplace harassment to backlashes from our conservative community, from the lack of intermediate nursing care facilities to difficulty getting around our sprawling metropolis, from getting legal help to finding affordable counseling, and from buying groceries and cooking meals to finding a place to live when you're out of money. Where are the public funds to solve these problems, to support social services, to provide education, and to help the person with AIDS live and die with dignity? Where do you turn in a city that ignores you? Where do you hide in a community that shuns you?

Investigational Drug Protocols

The policies, procedures, and bureaucratic sluggishness of the Food and Drug Administration (FDA) and National Institutes of Health (NIH) have delayed important human trials of investigational drugs to treat AIDS. At the same time, such regulations have kept experimental treatments away from patients who desperately need them. Such problems, at a time when the deadly epidemic continues to expand, is leaving researchers dismayed and patients distraught.

Perhaps the most significant issue involves the insistence on prospective, parallel, *placebo-controlled* phase III clinical trials for drugs shown effective and safe in phase I and II trials. While such conservative forms of scientific study serve to protect patients from untoward side effects, drug interactions, and other unknown sources of harm and also serve to validate the scientific merit of such trials, this epidemic demands a more rapid and innovative response from the involved Federal agencies. Further restrictions, requirements, and exclusions denying patients drugs are based upon narrow and conflicting clinical definitions, concomitant therapies, and combinations with other investigational drugs in patients commonly needing cancer chemotherapy and/or antibiotic treatment for infectious diseases.

In the face of a fast-growing, infectious, life-threatening epidemic predicted to afflict two million Americans by 1991, it occurs to many of us that we must have the courage to move from traditional activities which have served us well in the past to a position that is dictated by the present and required by the future. There are scientifically-acceptable methods of testing these investigational drugs which are more humane. AIDS demands such innovations.

And finally, there are overwhelming practical concerns to consider. One is simply adequate funding of these drug trials as quickly as possible in hopes of finding useful treatments before the epidemic expands to horrifying proportions, overburdening our health care and social service systems. Another very real practical concern is that potential participants in drug research protocols, facing impending suffering and death, and aware of restrictions, exclusions, and placebo controls, are seeking alternative ways of improving their health and survival. This exodus from research centers leaves drug trials stifled, and in the long run, we may all suffer the consequences.

AIDS ISSUES
AIDS Research and Education

TUESDAY, SEPTEMBER 22, 1987

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Washington, DC.

The subcommittee met at 2:10 p.m., pursuant to notice, in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. The meeting of the subcommittee will come to order.

When this subcommittee first began its hearings on AIDS in 1982, the questions of research funding were controversial. Dollars-and-cents analysis were required for each proposal. Panels of scientific witnesses were needed to challenge the adequacy of budgets.

Thankfully, those times are behind us. AIDS research funding is supported broadly. No one needs to be convinced of the need for such activity.

Likewise, when it was first proposed, AIDS education—aimed at specific groups and the public at large, this was all extremely divisive at that time. Assuming that AIDS would only strike homosexual men and drug abusers, public education was said to be too hot to handle. When the Surgeon General proposed to tell school children about AIDS, he was deserted by many of his political friends. When a debate on a Sunday news show turned to condoms, it was the first time that word had been used on the air.

To some extent, those times are also behind us. Most people are convinced of the need for AIDS education, and most are prepared to be candid. No one believes that the same messages are needed for third graders as are used for drug addicts, but almost everyone agrees that targeted information is necessary.

Today's hearings are to start the second generation of this work. Having demonstrated that AIDS research is necessary, we must now make the government support work quickly and well. Having understood that everyone should be educated about AIDS, we must now make the lessons widespread, clear, and effective.

No doubt there will continue to be controversies about bureaucratic structures, about budgets, and about who should educate whom about what.

But we are making progress in the politics of AIDS, and I hope that over the next few months, we will make dramatically more.

Before calling on our witnesses, I want to recognize members of the subcommittee for opening statements, and first I want to call on the ranking minority member of the subcommittee, Mr. Madigan.

Mr. MADIGAN. Mr. Chairman, I think I have just unplugged somebody's microphone down here, and I apologize for that to whoever the owner of the microphone is.

Mr. Chairman, the vast bulk of Federal dollars earmarked for the AIDS crisis has been used to fund research. A significantly smaller amount has been dedicated for education and information programs. Almost none has been dedicated to public health regulation of the crisis.

While I recognize that the focus of today's hearings is research and education, I would be remiss if I did not point out the recent actions taken in my State of Illinois to deal with the AIDS crisis.

Governor Thompson of Illinois was presented with 17 bills relating to the AIDS crisis which had passed both houses of the State legislature. He signed into law 10 of those 17 bills. The legislation he signed will allow public health officials to trace AIDS victims' sexual partners. It will require AIDS testing for couples wishing to marry. It will allow public health officials to quarantine AIDS victims when there is clear and convincing evidence that the public welfare is significantly endangered, and it will allow judges to order that certain persons convicted of sex offenses or narcotics-related crimes be tested for AIDS. And finally, it will require schools to teach youngsters in grades 6 through 12 about sexual abstinence in order to avoid the AIDS complications.

I think that these actions are clearly more effectively handled at the State level than at the Federal level. I certainly do not urge that Federal lawmakers take the identical course that Illinois lawmakers have taken, but I do think that the Federal Government has an obligation to assure that States have adequate funds to address the AIDS crisis on a number of fronts.

Education and information efforts will be most effective if they are tailored to and by local areas. Testing programs will be most effective if they reflect the attitudes of local residents.

I hope that we keep this in mind as we decide how much to authorize for the AIDS crisis, and how authorized programs are to be designed. We must be sensitive, Mr. Chairman, to local needs, whether we are talking about research, treatment, education or public health regulation.

I hope that the witnesses will address the role of the Federal Government in assisting States during their presentations this afternoon.

Mr. WAXMAN. Thank you, Mr. Madigan.

Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

Mr. Chairman, education is an absolute prerequisite for stopping AIDS, and I want to commend you for holding this hearing.

The only point that I wanted to make at this time, Mr. Chairman, is that this spring, for fiscal year 1987, Congress appropriated $30 million for an AIDS education mailing to all American households. As of now, that mailing has not taken place. It is my understanding that the Public Health Service put together such a mailing; however, the plug was pulled on this education mailing at the White House. The subcommittee staff has been informed that a mailing will not take place during this fiscal year which is the period for which the appropriation was voted on by the Congress. I would hope, Mr. Chairman, that the subcommittee would look into this matter and find out what has befallen this $30 million appropriation. It is my understanding that the subcommittee staff has learned that it is not an education program that will occur, and I hope that we would inquire further into what has happened to that money.

I thank the Chair.

Mr. WAXMAN. Thank you, Mr. Wyden. We will join you in that inquiry, and I think it is appropriate that we find out why that money has not been spent as Congress determined it should have been spent.

Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

When Surgeon General Koop made his report to the Nation last October, as to what the Federal Government should be doing, one of the things that he mentioned in his report was the necessity of education. I think it is important that we pursue that. But there was a serious omission in Surgeon General Koop's report to the Nation last October, because he failed to recognize the inseparability of human sexuality and morality and ethics. That omission was corrected by a joint statement issued by Secretary of Education Bennett, joined in by Dr. Koop in January, and I think so long as the American government or any State or county government or school district in America seeks to educate the public of America on how not to get AIDS, so long as we recognize the inseparability of education or human sexuality with morality and ethics, we will be on the right course. But if we are curious as to how much education expenditures by the Federal Government have resulted in a decline of pregnancies among females in our society 15 to 19, we have only to look at the statistics that were gathered from what we spent in the decade of the 1970's, where we spent roughly—we increased expenditures from $80 million to $300 million, roughly a factor of four, and for that Federal expenditure of dollars we realized an increase of pregnancies of roughly 50 percent, and a doubling of abortions, and only a small decline of live births.

What this data tells me is this: When we seek to reduce human sexuality on the basis of Federal dollars spent on education, we have the assurance that we are going to produce one thing; namely, more human sexuality.

I am not sure that is the course we should be taking, but in light of the seriousness of the epidemic, maybe the result of expenditure of Federal dollars in education to reduce AIDS would be appropriate. We will listen to the witnesses, and hopefully we will make the correct judgment.

Mr. WAXMAN. Mr. Sikorski.

Mr. SIKORSKI. Let me just thank you and the witnesses for doing their part in this fight.

Mr. WAXMAN. Mr. Whittaker.

Mr. Walgren.

Mr. Bliley.

Mr. Bliley. No opening statement, Mr. Chairman.

Mr. Waxman. Mr. Dingell.

Mr. Dingell. I commend you for the hearings, and I wish you success in your undertakings.

Mr. Waxman. And Mr. Coats.

Well, we are pleased to call for our first witness, Ms. Ann E. McFarren, Executive Director of AIDS Action Council, and President of the AIDS Action Foundation.

Ms. McFarren, we are pleased to have you with us. We want to welcome you to the subcommittee hearing. I would like to ask you to proceed with your direct testimony. If you'll pull the microphone close to you, there is a button on the base, and push it forward.

STATEMENT OF ANN E. McFARREN, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL, AND PRESIDENT, AIDS ACTION FOUNDATION

Ms. McFarren. Mr. Chairman and distinguished members of the committee, thank you very much for having me speak with you today.

I am Ann McFarren, Executive Director of the AIDS Action Council, and President of the AIDS Action Foundation.

We represent 300 service providers around the United States that are providing social services and support services and education programs in the communities where they work.

During the time I have with you today, I would like to discuss the national education program that I believe is important in addressing this disease.

Public health officials have repeatedly indicated that we must control this epidemic by education. As a matter of fact, it is the cornerstone of our prevention efforts. We have no vaccine, we have no treatment or cure. We must rely on education efforts.

Reducing hysteria is another reason for a massive education campaign. The Ray family, who lives in Arcadia, FL, has not had a peaceful time, even though Arcadia means peace. Their fire was a tragedy. I believe it was a tragedy because of lack of good education programs.

Obviously many people in Arcadia were afraid of the HIV virus. They did not understand the infection; they did not understand its transmission; and they were fearful for their children.

I believe all of you have enough facts to know that those fears are groundless and we need more education for our general public to help them understand that. Because of the fear and the lack of information, we had a very tragic situation and, in my view, it was needless.

It is imperative that we have a national program starting now, and the council supports the recommendation of the National Academy of Sciences that there should be $1 billion spent on education by 1991.

I believe the appropriate goals are: helping our citizens understand the disease, its management and its transmission; assuring that people who are ill receive the appropriate care, compassionate response from their neighbors, from their friends, and from health care workers; and help people identify sources so that they can find out more about AIDS, if they would like to, or feel they need to know.

We recommend a broad program, and most of the information in that is submitted in my written testimony.

I feel that the programs that other countries have developed could help us and be a guide as we develop the programs that should be done in this country.

While we have debated the appropriateness of education and what should be in the messages, England, France, Australia, Uruguay, Brazil, Switzerland and other countries have in fact implemented programs.

I have submitted to you information on the numbers of cases of AIDS in the countries that I just mentioned. I won't mention them all now, but Switzerland has 266 cases; Canada has 1,000; France has almost 2,000; and the United States has 41,700 and some cases.

Surely those figures should help us move forward in this effort.

The television clips and the movie clips that I am going to show you now are those that are developed and used in other countries. They may not all be appropriate here, but I think the thing that is important about them is that each one of these countries has assumed the responsibility of educating all of their citizens.

I thought you would like to see them as samples of things that are available.

The last tape that will be shown, which is the Swiss tape, is not a television spot; it is rather a spot that is shown in movie houses. We do have additional copies of the tapes if you would like them.

If we could have the lights down and show the tapes now, please.

[Media footage played.]

Ms. McFARREN. Mr. Chairman, we do have additional information on education programs from these countries and others, but I felt that was just a sample that you might like.

Our Nation's commitment to informing and educating our citizens is paramount if we are to stop this epidemic. Each day we wait to implement education programs like those I have described and others, additional people are being infected with the virus. In 1992 they will start to become the tragic statistics of this disease.

People are dying one by one every day. Our inaction means that right now we are signing the death certificates for people who will die in the next decade. We must not allow this to continue.

Thank you.

[Ms. McFarren's prepared statement follows:]

STATEMENT OF ANN E. McFARREN

Good afternoon Mr. Chairman and distinguished members of the subcommittee. Thank you for the privilege to appear before this subcommittee.

I am Ann McFarren, Executive Director of the AIDS Action Council and President of the AIDS Action Foundation. The Council was established 3 years ago by the AIDS service providers. Today the Council represents over 300 of these groups which provide direct social services, support services and community education in cities throughout the United States.

Recently the Council established the AIDS Action Foundation as its educational arm. The Foundation is responsible for legislative research, training and educational programs for public activities.

During my time with you today, I will be discussing efforts to inform this Nation's public about AIDS.

Public health officials have repeatedly stated that to control the epidemic we must educate the American public about AIDS and its transmission. We have no cure for AIDS. We have no effective long-term treatment. Vaccines will not be available until at least the mid 1990's; if ever. Thus, education is the cornerstone of our National AIDS prevention effort. Reducing hysteria adds another compelling reason for massive public education programs.

The Ray Family lives in Arcadia, FL—Arcadia means peaceful—yet their lives have been far from peaceful. The tragedy of the Ray Family fire, is directly attributable to the total lack of appropriate education and leadership in the area of AIDS education. It is obvious that some Arcadians were frightened of the disease, clearly they did not understand HIV infection and transmission, and they believed that their children were at risk. Fear which resulted from a lack of information was our enemy and ended in needless tragedy.

Political, religious, health and business leaders must join together to assure that all of us have the knowledge and understanding of this disease, so tragedies such as the Ray fire will never occur again.

Another example of an inappropriate response to AIDS is the Montgomery Alabama Police listing of "suspected AIDS people" to protect rescue workers and police. Lists and tests won't protect service people from infection; education, and training will.

The facts and problems before us make it imperative to launch a massive national education program now. The Council supports the National Academy of Sciences' recommendation to provide $1 billion of Federal funds for education by 1991.

The goal:

1. Helping our citizens understand the disease, it's management and transmission.
2. Assuring that people who are ill receive appropriate and compassionate response from their neighbors, friends and health care workers; and
3. Identify resources so that any American can find out more about AIDS.

A broad sweeping program should include the following components:

Federal and private sector support for a national educational campaign on AIDS.

Implementation of local public information programs as an adjunct to National campaigns.

Development of targeted educational programs.

Expansion of School Health Programs.

Expansion of programs for the development and training of AIDS educators.

The general public education campaign should include advertising spots that must be creative, tasteful, attention getting, compelling provide accurate information and shown during prime time.

Continued prime time coverage of AIDS issues will enhance the public's awareness.

Utilization of sitcoms is another educational opportunity that should be accessed.

Print media efforts must parallel the electronic media.

Nations around the world have informed their citizens about AIDS in an effort to control the AIDS epidemic. These countries have launched massive education campaigns. The most successful include campaigns that provide a coordinated approach with prime time televised messages, printed material, trained health professionals prepared to answer to the public's response to the campaign, house to house informational mailing, and education campaigns in the schools.

While Americans debate the appropriateness of educational materials—England, France, Australia, Uganda, Brazil, Switzerland and others have implemented programs.

The cases of AIDS reported in these countries are:

Switzerland	266
Australia	583
Great Britain	935
Canada	1,000
Uganda	1,138
Brazil	1,625
France	1,980
United States	41,735

As of September 17, 41,735 cases of AIDS were reported in the United States. Six years later into the epidemic, no government sponsored national educational program has been launched.

Today, I have brought with me examples of educational TV spots which have been developed for use in government sponsored national education programs in several of the countries I have just mentioned.

I could discuss with you at length the TV clips I am about to show you. Prepare you for their impact; good points and bad points. However, I think that the TV clips speak for themselves. The point I would make with you is that each of these Nations have assumed the responsibility of educating its citizens.

The Australian, United Kingdom's campaign have been effective tools in raising the publics awareness of AIDS. Some critics complain that the commercials have unjustly scared the public. However, we can learn from their mistakes, and move forward. A prime time television campaign creates an aware public. Public awareness is the first step to educate the public.

Mr. Chairman, with your permission I would like to have the committee review these clips now. None of them are sexually offensive or explicit, instead, they are creative and compelling and provide accurate information about AIDS to the viewers.

In addition to a media program, other educational programs are necessary to meet the challenges this epidemic poses. Targeted education programs represent a major challenge to our efforts. Fortunately, we have some models that have been developed in the last few years that are working. Targeted education differs from general public education, by aiming at groups of people who are considered to be at higher risk of contracting or transmitting the virus. Programs for these groups must be culturally sensitive, very clear, explicit and provided in environments that are comfortable to the individuals who must receive the message.

The gay community has done an excellent job of educating their members. These programs are based on understanding peoples behavior, they provide clear information, respond to concerns of people regarding disease transmission and worked to develop a culture that decreases the risk of transmission. Programs have ranged from "clean and sober" campaigns to safer sex education. While has been very difficult to quantify successes, a recent study in San Francisco has indicated about an 85 percent drop in the STD rate among gay men; this shows that programs can have a substantial impact.

Other groups that need specific, targeted programming include IV drug users, prostitutes, sexual partners of other persons in high risk groups, minority groups, school aged and college populations and health care workers.

We have recently heard of tragic accidents leading to infection of health care workers. Training programs to ensure that appropriate body fluid precaution techniques are followed must be implemented. If health care workers rely on testing information for patient management they will have a false sense of security. Programs for rescue workers, such as those in Montgomery, AL, should be offered education and training under this segment.

Health care workers must also have accurate information to provide appropriate guidance and education to their patients.

The expansion of school health programs is another area to be addressed. School boards around the country are beginning to develop core education programs, national organizations are beginning to address the issues, a massive program is urgently needed. All school boards, PTA's and teachers associations should make a commitment to assure quality, accurate AIDS education in their school systems within the next year. A substantial investment will be needed for teacher training, in order to accomplish this goal.

Our Nation's commitment to informing and educating its citizens is paramount in controlling this epidemic. It is the only "vaccine" we have. Each day that we wait before we implement the educational programs I have described—additional people are being infected with the virus. In 1992, they will be part of the tragic statistics of AIDS. Mr. Chairman, people are dying of AIDS, one by one, every day. Our inaction today means that right now we are signing the death certificates of people who will die in the next decade—we must not allow this to continue.

Thank you very much for the opportunity to discuss our views with you today. I will be happy to answer any questions you may have.

Mr. WAXMAN. Thank you very much for your testimony.

I gather those films were made by those countries, by their governments?

Ms. MCFARREN. Yes, they were.

Mr. WAXMAN. To try to inform their people about AIDS and ways to lessen the risk of the AIDS epidemic.

Ms. McFARREN. Yes.

Mr. WAXMAN. How many film strips have been made by the U.S. Government?

Ms. McFARREN. I am aware of one set of spots that Governor Bowen—excuse me, I'm from Indiana—Secretary Bowen has given that simply states that AIDS is a concern and gives a hotline number. None of this type of filming.

Mr. WAXMAN. And then there are announcements for television being made by private organizations that are aired as public service announcements.

Ms. McFARREN. Yes, there are, although there is no campaign that is an integrated campaign that provides information at all levels and is targeted for prime time in key information slots, and that is one of our major concerns. Frequently public service announcements are aired at 2 or 3 o'clock in the morning, and that is not when many of us are listening to television.

Mr. WAXMAN. Are these spots being aired during the prime time television viewing hours in the respective countries?

Ms. McFARREN. A good share of them are. Some of them are not.

Mr. WAXMAN. Thank you very much.

Mr. Madigan.

Mr. MADIGAN. Ms. McFarren, with regard to the video announcements you have just shown us, can you tell us what the impact of those announcements has been in the countries in which they are shown? For example, has there been any community resistance to these commercials, and has there been any attempt made to measure the effectiveness of the commercials?

Ms. McFARREN. There have been studies done in England regarding the response to the English campaign, which included not only radio and television materials but a door-to-door mail campaign. It did increase people's awareness and knowledge, and there is a fairly extensive report on that entire program which I would be glad to submit to you.

Australia has also done a fairly extensive response, and I don't happen to like that particular spot because I think it is very frightening, but over 97 percent of the population in Australia indicated that they had seen the spot and could describe it when they were tested in market surveys afterwards. Seventy-five percent said that it increased their knowledge, and 70 percent indicated that it did change their behavior.

So it appears that there has been some effect from this type of effort in other countries.

Mr. MADIGAN. In those countries the networks are government owned, so I presume the networks had some say in determining at what time the announcements would be seen by the public.

Ms. McFARREN. Yes, and that, of course, is a difference here. In our case I would hope there would be a public/private effort to assure that information was shown during prime time, but it would no doubt be much more expensive in this country than it would be in a situation like that of England.

Mr. MADIGAN. Do you know what years, for example, with regard to France or Australia, what years these video presentations began to be displayed publicly?

Ms. McFARREN. I believe I have that data but I do not have it with me, and I can get it for you.

Mr. MADIGAN. You use numbers. You said there are 2,000 cases of AIDS in France.

Ms. McFARREN. Almost 2,000.

Mr. MADIGAN. And 41,000 in the USA.

Ms. McFARREN. Yes.

Mr. MADIGAN. The inference in your remarks would suggest that you believe the difference between the levels of infections in the two countries has been the educational programs. Is that the inference that you wanted me to draw?

Ms. McFARREN. No, sir, it was not. My concern is that we know we have many, many people who have already been diagnosed with AIDS, and we are aware that there are many people who are infected in this country, and in order to avoid further transmission, it is imperative that we start a major education campaign.

When many of the people who are now ill were infected, we did not even know enough about the disease to tell people what they might do to prevent transmission.

Mr. MADIGAN. From your work and interest in this issue, do you think these numbers for these other countries accurately reflect the situation in those countries presently?

Ms. McFARREN. My understanding is—and this is verbal and I don't have documentation on it—that the data basis for the countries I mentioned, with the possible exception of Uganda, are fairly accurate. When we get to the emerging Nations, we have a different problem, but generally health data in the other countries that I mentioned is fairly accurate. Another problem may be Brazil.

Mr. MADIGAN. Thank you very much.

Mr. WAXMAN. Thank you, Mr. Madigan.

Mr. Wyden, questions? Mr. Dannemeyer, any questions?

Mr. DANNEMEYER. Tell me, Ms. McFarren, does any of the money that finances the work of your foundation come from the Federal Government?

Ms. McFARREN. No, sir, it does not.

Mr. DANNEMEYER. And how long have you been in business?

Ms. McFARREN. Three years.

Mr. DANNEMEYER. I was interested in the films you showed, and I have a comment with respect to two points. At one point, one of the film narrators made the statement that the only means of transferring the virus is by sex or drugs. Are you aware that of the 41,000-plus AIDS cases in this country, CDC has categorized between 3 and 4 percent as unknown as to source?

Ms. McFARREN. Yes, I am.

Mr. DANNEMEYER. Your film doesn't say that, does it?

Ms. McFARREN. Sir, I am aware that we don't know all the sources of transmission. I believe that in some cases when the histories were taken, people were ill and were unable to give appropriate information. However, these particular films are an indication of what another country elected to do. I am not suggesting that we should use these films as they are in this country. I am suggesting to you that these are models from which we could draw to develop our own education program so that we could address this very serious problem.

Mr. DANNEMEYER. There was a statement in one of the films with respect to the use of condoms. Did the film say the failure rate for condoms with anal intercourse?

Ms. MCFARREN. No, it did not.

Mr. DANNEMEYER. Do you know what that is?

Ms. MCFARREN. I'm not sure that we have any good data on that.

Mr. DANNEMEYER. Would you believe that the estimate of 30 to 40 percent of failure with the use of condoms for anal intercourse is accurate?

Ms. MCFARREN. That would certainly be much higher than the pregnancy rate with using condoms, and that is the only, I think, relatively accurate data we have in terms of condom usage in this country.

Mr. DANNEMEYER. The film also mentioned in the use of condoms—well, it didn't mention anything about the failure rate of condoms for vaginal intercourse, did it?

Ms. MCFARREN. No, it did not.

Mr. DANNEMEYER. Do you know what that failure rate is?

Ms. MCFARREN. Yes. That is about 12 to 15 percent use efficacy rate, which indicates not only those people—that takes a data of 100 couples having sexual intercourse for a year, and about 12 to 15 of them would become pregnant. A number of those would become pregnant because they did not use condoms rather than because of the failure of the condom.

Mr. DANNEMEYER. I only mention this point to point out that if our message to the American people is that we can avoid getting AIDS by use of a condom, we are deceiving ourselves and the people of the country. There is no such thing as safe sex. There may be safer sex——

Ms. MCFARREN. I would agree with you on that.

Mr. DANNEMEYER [continuing]. But it is kind of like taking a pistol with one bullet in it when you use a condom and have intercourse with a person with a fatal disease. You might make it five times, but you might hit the unlucky time once. I think if we want to be fair with the people of our country, we should be telling them that. Don't you agree?

Ms. MCFARREN. I certainly agree that condoms offer safer sex rather than safe sex. I would, however, prefer to have someone use condoms rather than nothing. The gun that you mentioned has one bullet in it if someone is using condoms. It would have six bullets in it if they were using nothing.

Mr. DANNEMEYER. Your foundation is in business for the purpose of education; correct?

Ms. MCFARREN. That is true.

Mr. DANNEMEYER. May I suggest there is another agenda this Nation can pursue in order to control the epidemic, and it relates to the pursuit of normal, routine, customary responses that our public health authorities have pursued traditionally to control communicable disease, such as reportability, and since we haven't been reporting those with the virus, now we are talking about testing certain samples of our population. I would suggest those topics for consideration by your board of directors as something we should be doing and hope you will find your way clear to support them.

Thank you.

Mr. WAXMAN. Thank you, Mr. Dannemeyer.

Mr. Sikorski. Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Ms. McFarren, your Council and your statement has called for $1 billion for education by 1991. Is that $1 billion a year or is that the total to be spent between now and 1991 would be $1 billion?

Ms. MCFARREN. Our goal and the recommendation of the National Academy of Sciences is that funds be increased in education to parallel the increase in research so that there would be, under their recommendation, $1 billion spent in research by 1991 annually and $1 billion spent in education by 1991 on an annual basis.

Mr. BLILEY. I am sure that you and your Council are aware of the budgetary constraints that we find ourselves, and it doesn't appear that we are going to get out of them anytime soon.

Ms. MCFARREN. Yes, sir, I am.

Mr. BLILEY. Has your Council ever considered perhaps a tax on condoms to pay for it? After all, somebody has got to pay for it.

Ms. MCFARREN. Frankly, we have not. The concept has a kind of nice ring to it. On the other hand, because we are talking about death, I would prefer that we perhaps tax something else and give away condoms so people will use them.

Mr. BLILEY. Well, perhaps if there is something else that is going to be taxed, they may not feel the same way as you do.

Ms. MCFARREN. I am sure that we might disagree on that.

Mr. BLILEY. In my experience in government, most people would like somebody else to bear that burden.

Ms. MCFARREN. I understand that. I am just concerned about the public health implications on this one.

Mr. BLILEY. Thank you, Ms. McFarren.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Coats.

Mr. COATS. Thank you, Mr. Chairman.

Welcome to a fellow Hoosier.

Ms. MCFARREN. Thank you.

Mr. COATS. I appreciate your efforts in this regard. I am wondering if you would comment more on the film clips that we saw. Those appeared to be directed to the adult population. Would you suggest that we might fashion a different message for different age groups? Is this something that you have considered, and if so, what would that different message be?

Ms. MCFARREN. Yes. I think that we do need to seriously think about what messages are appropriate for what age groups and for what populations. However, we should have a broad program that discusses education that is acceptable and done on national television and through national media and with sitcoms and every other way that we can. Then with specific groups, we would provide specific education that would be more detailed and at a level of understanding that would be appropriate for that group.

Clearly, people in young grades need basic information and, more important, I think, a feeling of self worth so that they can make their own independent decisions and feel strong as they grow up. As they get older, they need more specific information.

There are now some very excellent education programs out that make recommendations, K through 12, for AIDS education. I would be glad to provide some of those for you if you would like.

Mr. Coats. Do any of these countries that are engaged in the national program have different spots for different age groups? Are you just showing us an example of what is shown on national television?

Ms. McFarren. Those are national television films with the exception of the last one, and there are other vehicles and educational materials for age groups and for specific populations in most of those countries.

Mr. Coats. Who has done the best job of all? What country do you look to in terms of educating and informing its citizens?

Ms. McFarren. Certainly Great Britain's program has had all of the components that we think are so important, from the major television programs to education, educational efforts on TV, mailings to people's homes, and segmented education programs. So they designed a nationwide program, and I think that is very successful. I think we are still evaluating all of the programs, and each one of us can improve on the last person's and last country's efforts.

Mr. Coats. Thank you.

Thank you, Mr. Chairman.

Mr. Waxman. Thank you.

Mr. Fields.

Mr. Fields. I really just have one question. I recently sent out a general newsletter, one of what are called Postal Patrons to my constituents, on the subject of AIDS which contained general information. I represent what would be termed a Bible Belt district in the South, in Texas. I was pleasantly surprised at the response I got. The people were grateful that I had sent out that particular type of information as a public service.

So my question is: Are there other things that you might suggest that we as concerned members of Congress might be able to do to help in that educational effort?

Ms. McFarren. I certainly think that information that is sent out as part of your communication with your constituency is very helpful. Some members of Congress have sent out the Surgeon General's report to all members of their area, and that has been helpful.

I think what we are going to have to realize and one of the dilemmas we face on this is this has to be an ongoing process. First of all, people forget, we need reinforcement, there is new information coming out. People hear things differently at different times in their lives. If they are not involved in a relationship and they don't care much about AIDS and they start to move into a relationship, they need more information.

So we must think in terms of a long-term program with ongoing information to assure that all of our citizens have the information that they need. All of those kinds of efforts are useful.

Mr. Fields. What is the best clearinghouse for that information? Is it the Surgeon General's Office?

Ms. McFarren. At this point the Surgeon General certainly has some excellent information. The National AIDS Network also has information on materials that are available around the country, and I believe, although I am sorry to say I do not believe it is yet funded, that eventually the Centers for Disease Control will have a major clearinghouse. It was originally my understanding that that was to be funded this year. I have not heard that the contract has yet been approved.

Mr. Fields. Do you know, or perhaps the chairman may know, does the Surgeon General plan to update or amend his report?

Ms. McFarren. I am not aware that he is going to update it, but I haven't checked lately, either.

Mr. Fields. Do you know, Mr. Chairman?

Mr. Waxman. I am not aware of the Surgeon General making any changes or updating it, but I think the Public Health Service is working on keeping it up to date.

Mr. Fields. Thank you very much.

I yield back.

Mr. Waxman. Thank you very much for your testimony to us and sharing the film clips with us and talking about the educational efforts. We appreciate you being with us.

Ms. McFarren. Thank you, Mr. Chairman.

Mr. Waxman. Our next witness is well known to everyone, not just to everyone here but maybe everyone in the world. Ms. Elizabeth Taylor has taken the opportunity of using her tremendous popularity and renown to turn America's attention to the problems of AIDS. She and the organization she chairs have begun a private effort to create a compassion and urgency in our response to the epidemic.

I want to welcome you here today and commend you for your leadership and tell you how pleased we are to hear from you at this hearing this afternoon.

STATEMENT OF ELIZABETH TAYLOR, NATIONAL CHAIRMAN, AMERICAN FOUNDATION FOR AIDS RESEARCH

Ms. Taylor. Thank you. It is very nice to be here. Thank you for the introduction.

I am Elizabeth Taylor, the National Chairman of AMFAR. We started about 2 years ago, and I am very pleased to say that we have already given away in 50,000 grants approximately $3¼ million, and we are very proud of that for a young foundation.

Chairman Waxman, Mr. Madigan, I am very honored to be here and thank you.

Let me begin by expressing my heartfelt gratitude and admiration for the Congress' success at increasing the levels of AIDS spending. Your remarkable achievements have not gone unnoticed.

I am here today to discuss the AIDS crisis. I emphasize the word "crisis." We must keep in mind the fact that AIDS is a crisis, an overwhelming crisis that grows with each new day, one that threatens hundreds of millions of people worldwide, a crisis that is measured not only in human lives, tragic suffering and untold economic costs, but also one that tests our capacity for reason and compassion.

Our most wished-for hope to stopping AIDS is obviously a cure and a vaccine. This requires an intensive, expeditious, well-funded, well-coordinated research effort. The battle to continue increased funding will obviously be difficult. I beg you to persevere in providing the funds to find the answers that are so desperately needed. If the answers are not found quickly, all budgets will be totally overwhelmed.

We must always keep in mind that we are facing an emergency. Federal research programs must not be only funded; they must be guarded against bureaucratic delays.

Scientists at the CDC and NIH have expressed their opinion that they must also pursue long-range plans that don't necessarily fit into the year-to-year plans. We have been told that even when research projects are improved, oftentimes the researchers cannot get staff or laboratory facilities. "For want of a nail, the war was lost." Don't let it be that for want of a lab, the countless human lives are lost.

In the absence of a cure or a vaccine, we have only one weapon to combat the spread of AIDS. That weapon is education. In Britain, population 55 million, 750 cases of AIDS have been reported. Government-sponsored AIDS education campaigns have totalled $30 million. In the United States, population 234 million, 41,700 cases of AIDS have been reported. No public information or media campaigns have been initiated. One million dollars has been appropriated to develop a national advertising campaign. In excess of $20 million is awaiting congressional action to support a mailing and education program for AIDS information to all households in America.

AIDS education must be forthright and understandable. We must be explicit without being vulgar, yet we must use words that everyone will understand instead of euphemisms that are vague and unclear, and we must not spread fear or panic in our education.

We must separate the facts of AIDS education from the lessons of morality. We are not talking about a venereal disease for which one can take a pill or a shot; we are talking about life and death. The prevention of effective AIDS education due to claims of immorality may lead to the deaths of many Americans to whom morality was emphasized over reality.

There are many things that must occur in order to put an end to this epidemic that is just killing so many people. There are also some things that must not occur. There is no place in the fight against AIDS for business-as-usual complacency or politics. It has nothing to do with Democrats and Republicans.

As election year approaches, AIDS is already becoming a political issue. There are those who say that those of us who want to educate and guarantee research to save lives are a special interest group. Those who are sick are being blamed for being sick. We are see growing numbers of examples of the most cruel and senseless mistreatment of people with AIDS.

We are at war with a virus; we must not be at war with each other.

I thank you for your hard work, and I urge you to continue to fight for the day when AIDS will be nothing but a painful memory.

Mr. Waxman. Thank you very much, Ms. Taylor, for that excellent statement. Obviously, your organization has been trying to get the research funds to develop a cure or a vaccine, but what we now have as a way of stopping the spread of this disease is education and only education. Unless people know the information about how AIDS is spread and how it is not spread can they take the actions that will be necessary to protect themselves and not take actions that are based on irrational fears, which will be doing an injustice not just to them but to everyone involved.

Ms. Taylor. Exactly.

Mr. Waxman. What do you believe would be the most effective way of reaching American audiences with AIDS education?

Ms. Taylor. I think the media can and has been very helpful, but I think they are also very misguided. Sometimes I am watching the news and I go through the ceiling. You hear facts that aren't substantiated, and I suppose they get their information from the CDC, but the information seems to change daily. The facts seem to change daily. We seem to be spreading panic and fear more than education, more than ways of preventing the spreading of disease.

We do know that it is through sex, blood, drugs that it is spread, but we must learn the practical ways of avoiding that. It is all fine and well to say abstain from sex, but that is not a practical answer. I don't think everyone in America that isn't married is all of a sudden going to stop having sex. I think that is a totally unrealistic approach.

It is a catastrophe that condoms aren't 100 percent foolproof, but they do help. It does lessen the chance, but some people still believe that AIDS is a homosexual disease and that only homosexuals should worry about it, that it is in their court. That is totally untrue. It started out a heterosexual disease in Africa from eating the green monkey. If you really want to get down to it, everybody who isn't a vegetarian should be rounded up, I mean if you really want to get silly about it.

It is a disease now that belongs to everyone, and it picks at random. The only way of slowing it down is through education. I don't believe myself in education in schools. I think it should be at home through parents. But I think this is a case where, because parents themselves know so little about it, it is going to have to be taught in schools in a way that doesn't spread fear and discrimination.

Mr. Waxman. In other words, we have to be honest about what we know, what we don't know, but what we do know is a great deal about this disease, and we have to be honest with people about how the disease is spread and ways to lessen the risk.

I was troubled by some of those ads that I saw where they acted as if condoms were a sure answer to stop the spread of AIDS.

Ms. Taylor. And unfortunately, it is not.

Mr. Waxman. It is a way to lessen the risk. It is a way to protect oneself if they are going to undertake this risk. I noted that the educational efforts of your organization have pointed that out over and over again, giving the information that we know to be factual based on what the scientists have told us, not what people want to fear or what they want to conjecture, but what information we have in being honest with people and trying to give some leadership to try to stop this epidemic.

Ms. TAYLOR. It is the behavior of tomorrow that is going to have to change, and I hope the behavior of today. I hope people start reacting with compassion toward the people that have AIDS and start acting like human beings towards their human mankind and not show what is happening now, man's inhumanity to man.

Mr. WAXMAN. I want to recognize other members of the subcommittee for questions they might have of you.

Mr. Madigan.

Mr. MADIGAN. At the outset, Ms. Taylor, let me assure you that to everybody over the age of 40, you are quite attractive with your glasses on.

And I am going to leave mine on because I quickly want to read you some numbers. In 1981 the total expenditures by the Federal Government on AIDS-related programs was $200,000, and in 1988 it is proposed to be $790 million. So in response to the initial part of your statement as to whether or not the Congress is going to be responsive to providing sufficient money for this, I think those numbers should alleviate any concern that you have.

This is a bipartisan effort. No Republican and no Democrat has spoken against this increase, and Republicans and Democrats have cooperated in making those increases possible. If the Centers for Disease Control and Dr. Koop and others want to come in and show us other ways that we can effectively spend more money, I am sure this subcommittee and the committee of which it is a part will be as responsive to those requests as we have been to all of the other requests that have been made since 1981.

But as you point out, as that money is being spent on various kinds of research, including research in search of a vaccine, the effective thing that can be done by American society is to deal with the education part of this effort. In your remarks you have suggested that the education effort needs to be forthright and explicit, and it is in that regard that I would like to ask you if you would be willing to be a principal in that education effort that you describe as necessarily being forthright and explicit.

Ms. TAYLOR. Yes, I certainly would, and I have tried to be in the past.

Mr. MADIGAN. Would you be willing to make television commercials that say, for example, there are 41,000 people on the streets of America who could kill you through sex; you better be careful? Would you be willing to do that?

Ms. TAYLOR. Yes, I would certainly do that. I have done PSA's in the past, and I have every intention of continuing to do them. I will say anything I have to that will help AIDS.

Mr. MADIGAN. All right. Would you be willing to join with Mr. Waxman, myself and others in beating up on some of these network people so that those announcements will be seen by the public in large numbers?

Ms. TAYLOR. I would be more than happy to.

Mr. MADIGAN. Do you think you could enlist the assistance some of your colleagues in the Hollywood establishment in that kind of effort?

Ms. TAYLOR. People in show business really are quite extraordinary. I don't consider myself in show business, I have been out of it so long. I am talking about the people that are working. We already have 38 PSA's, not just for AMFAR, not asking for money, but informative PSA's, and we have 38 superstars that have volunteered and done them. So I think the entertainment world has shown more than willingness; they have done something about it. They have given of their time and their energies and they are continuing to do so, and they can be counted on for their continued support.

Mr. MADIGAN. I appreciate very much what you and others have been doing and what I know you will continue to do. We may be calling on you to say some chosen things about some of the network producers, or not producers but whoever these people are that own these things. Thank you.

Ms. TAYLOR. I'm here.

Mr. WAXMAN. Thank you, Mr. Madigan.

Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

Ms. Taylor, I to want to commend you for a superb job. My colleague asked for your help with the entertainment industry and the networks in particular. I would like to ask for your help with the Executive Branch of the Government of the United States.

Ms. TAYLOR. I have been trying. I was here a couple of years ago, and I must say the increase in the money has impressed me enormously since I was first here. It is wonderful.

Mr. WYDEN. There is one thing in particular that I think you could help us with tremendously. I noted that at the bottom of page 2 of your testimony, you said that $20 million is awaiting congressional action to support a mailing and education program of AIDS information to all households in this country. This spring Congress appropriated $30 million for an AIDS education mailing to all the American households for this fiscal year.

Ms. TAYLOR. That is such an important way of getting the message across to the American household. It starts with the parents. The parents can teach the children. It has worked in Britain. I will do anything I can to help you get that money. I will ring doorbells.

Mr. WYDEN. Well, I think perhaps one telephone call will do.

Ms. TAYLOR. That easy?

Mr. WYDEN. In fact, ringing the doorbell at 1600 Pennsylvania might help.

Ms. TAYLOR. Oh, I know that address.

Mr. WYDEN. I just want to commend you for a superb job, and if there is any way we could free up that money in the Executive Branch it would be wonderful.

Ms. TAYLOR. Would that be the place to call?

Mr. WYDEN. That would be just great.

Mr. WYDEN. I want to emphasize what my colleague from Illinois said about pursuing this on a bipartisan basis. The fact is that there seems to be some kind of bottleneck in the Executive Branch given that this money was appropriated for fiscal year 1987, and our subcommittee counsel has learned that it is not going to be spent in fiscal year 1987. In particular if there were efforts to make the money accessible, that money, I think that it would be a tremendous boost to the educational effort.

Ms. TAYLOR. It certainly would. I will try.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Dannemeyer.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

Ms. Taylor, I want to express my thanks to you in the work that you are doing with the American Foundation for AIDS Research, in the compassion you are exhibiting and the success I think you are having in focusing on what may be some solutions to this problem in the country.

I would like to ask you a little bit about the American Foundation for AIDS Research. Is a man by the name of Melwyn Silverman working for it?

Ms. TAYLOR. Melwyn Silverman?

Mr. DANNEMEYER. Dr. Silverman?

Ms. TAYLOR. Dr. Silverman. Merv Silverman.

Mr. DANNEMEYER. Merv Silverman? Yes. Is he working with the association?

Ms. TAYLOR. Yes, he is spokesman.

Mr. DANNEMEYER. What is his capacity with the association?

Ms. TAYLOR. Spokesman.

Mr. DANNEMEYER. Is that a full-time job for him?

Ms. TAYLOR. No.

Mr. DANNEMEYER. I see. And where does Dr. Silverman office in the capacity that he has, in California?

Ms. TAYLOR. He lives in California, I believe, in San Francisco. He has another job. He is part-time with us.

Mr. DANNEMEYER. I see. The reason I raised the question is because in this era in which we live, which is new to all of us, namely, faced with an epidemic, it is important that we have leadership in Congress, in the public health world and in work that you are doing that reflects the sense of treating this epidemic as a public health issue rather than a civil rights issue.

The reason I draw reference to Dr. Silverman is for you to take up with the board of directors of your association Dr. Silverman's status with your group. The reason I make that statement is that during a period of approximately from May of 1983 through October of 1984, Dr. Silverman was serving as a health officer for the City and County of San Francisco. In May of 1983, in June of 1983, in March of 1983 and then again in March of that year, he was asked by the political leadership of that city to shut down the bathhouses of San Francisco as a means of controlling the transmissibility of this fatal virus, and he refused. He declined to do it.

He was literally begged by the political leadership of that city to perform that act, which was within his jurisdiction as the chief health officer of the City and County of San Francisco. He finally made that decision in October of 1984 and resigned 2 months later because obviously there was some talk that he was on the verge of being terminated.

I mention this because, as I said at the beginning of my comments, we are going to be successful in this battle if the leadership——

Ms. TAYLOR. If I may interject?

Mr. DANNEMEYER. Go ahead, Ms. Taylor.

Ms. TAYLOR. That was before Dr. Silverman had anything to do with AMFAR, and the dates which you talk about, one knew so much less about the disease and how it was spread. What Dr. Silverman did then is entirely his own business.

How he behaves as a member of our Foundation is my business, and the board's business. He certainly has never given any indication that he would approve of those measures today.

Mr. DANNEMEYER. Well, I mention it because——

Ms. TAYLOR. I think he realizes that the way the disease is being spread that those particular things are not really a good idea.

Mr. DANNEMEYER. I mention it today because I probably won't have an opportunity of visiting with you again during our lifetimes.

Ms. TAYLOR. Oh, I don't know.

Mr. DANNEMEYER. It's not that I don't want to, but—you know. You have things to do and I have things to do.

Dr. Silverman is not only associated with your corporation, but he is also a spokesman for the California Medical Association. I think it is a mistake a judgment for we Californians—if I may speak this way—to have a person of the philosophical persuasion of Dr. Silverman in a sensitive position of attempting to lead——

Ms. TAYLOR. But I don't believe Dr. Silverman believes that today. He has never expressed that opinion to AMFAR.

Mr. DANNEMEYER. I only wish that were so. Ms. Taylor, I only wish that were so. It has been nice to visit with you.

Mr. WAXMAN. The Chair will take this prerogative to——

Ms. TAYLOR. I think you are condemning a man for something—I mean, people do change their mind. Dr. Silverman shows no indication that he thinks bathhouses should be open today.

Mr. WAXMAN. The Chair will address this point. I didn't do the research because I didn't think Dr. Silverman was the topic for today's hearing. But, as I recall the events, and I didn't have a chance to check them, but I think as I recall reading the newspaper that Dr. Silverman took the exact opposite position that is being attributed to him.

Furthermore, I do know that he is not a spokesman for the California Medical Association, although I think he shares the same opinion that they have given, that has been the same opinion that Dr. Koop has expressed, and Secretary Bowen has expressed, with which Mr. Dannemeyer disagrees.

I think what Mr. Dannemeyer is probably offended about is that Mr. Silverman doesn't agree with him on a lot of these issues. But I would think we all ought to check that information carefully, and hear from him——

Ms. TAYLOR. I wish you would, because——

Mr. WAXMAN. I don't think it is fair to attack a man's character without having given him an opportunity to be heard.

Mr. DANNEMEYER. Mr. Chairman, you misunderstood my remarks. I didn't talk about the character of Dr. Silverman. I talked about his judgment in performance of a role as the chief health officer for the County of San Francisco. That's the only matter to which I speak.

I only mention it because I question whether or not a person who has exhibited that judgment in the past should be associated with an organization that, ostensibly, is designed to reduce the incidence of this disease among the American people.

Ms. TAYLOR. I would like to know whether—excuse me—whether your facts are correct or not, because it is a reflection on the Foundation. I do know that Dr. Silverman does not believe in that today. And that's all I can speak of, as the Chairman of the Foundation, of which he is spokesman.

I don't like to see his character maligned.

Mr. MADIGAN. Would the gentleman yield?

Mr. WAXMAN. The Chair yields to Mr. Madigan.

Mr. MADIGAN. I would just observe, Ms. Taylor, that you hung in there very well. Thank you.

Mr. WAXMAN. I think if you are going to question a man's judgment, he ought to give his rationale for his judgment; and also to know what his judgment was before we condemn him.

Mr. Sikorski.

Mr. SIKORSKI. No more questions, Mr. Chairman. Thank you.

Mr. WAXMAN. Mr. Whittaker. Mr. Bliley.

Mr. BLILEY. No questions, Mr. Chairman.

Mr. WAXMAN. Mr. Coats.

Mr. COATS. Just one question, Mr. Chairman, and one statement to make. My colleague, Mr. Madigan, asked Ms. Taylor if she would participate in a program which would send a message that there are potentially 41,000——

Ms. TAYLOR. Seven hundred.

Mr. COATS. Forty-one thousand people who currently have AIDS and that, if you had sex with them, it could kill you. That particular message. I think it is important, and I know Congressman Madigan knows this, but I think it is important that everyone understand that the estimates are that, for every person currently infected with AIDS, there are 100 people carrying the AIDS virus who don't know it.

Ms. TAYLOR. Exactly.

Mr. COATS. So we are talking about 4 million people, not 41,000 people.

Ms. TAYLOR. All the people that have ARC and are carriers, and don't know it. The women, particularly there is a very high percentage of women carriers with ARC, that have no idea they are carrying ARC, because they are not looking for the symptoms.

Whereas a man may be more on the lookout for such things as swollen lymph glands, and various other things. It may not occur as readily to a female. I believe, in New York City, last week they tested at random in a hospital 5 percent of the pregnant women that had come to the hospital for treatment, and 5 percent of those women tested that were pregnant had AIDS.

They couldn't inform the women, because they had not been told they would be tested. That's an amazing percentage, just from one hospital.

Mr. COATS. I think it is important to publicize the potential scope of this epidemic and the crisis that we are facing. The word you used was crisis, and I believe it is crisis, and we should act accordingly.

You have had children of your own, and many of the members on this panel have teenagers. What message should we be sending to our teens today about this disease, this virus that kills, and what steps they should take to avoid it?

What would you tell your—I don't know the ages of your children.

Ms. TAYLOR. Mine are all grown now, but I have grandchildren who are growing up. I think the mores, the morality today simply have to change. If it means taking a complete swing, as it usually does, from a permissive age to a more Victorian attitude. This is with a reason, not just a fashion.

It is a life reason. People are going to have to change their ways. I think things like singles bars, massage parlors, are going to have to be a thing of the past. Careful sex: you cannot say to teenagers, people in their 20's, 30's, 40's, 50's, that sex is completely out of the question.

That is unrealistic. There have got to be ways of careful sex. We have to be more inventive, I guess, and have more fun in finding them.

Mr. COATS. Don't we run the risk of not giving them the full truth, if we talk in terms of safe sex, or careful sex?

Ms. TAYLOR. I think we have to tell them the complete truth.

Mr. COATS. The complete truth is that any relationship carries the potential——

Ms. TAYLOR. If you are talking about intercourse, yes.

Mr. COATS. Carries the potential of receiving the virus.

Ms. TAYLOR. Yes.

Mr. COATS. I am disturbed sometimes with the message that says, all you have to do is have one partner. Just make sure you don't have multiple partners. I am not sure I want to leave that message with my teenager daughter, because that one person may be carrying the virus.

Ms. TAYLOR. Exactly. I am a single woman, and I think before embarking on a new relationship I would have the AIDS test myself. If I were serious about someone, in love with someone, I would ask that they have the AIDS test before I embark on an intimate relationship.

Mr. COATS. The reason is because the consequence is death. No cure.

Ms. TAYLOR. There sure isn't.

Mr. COATS. It is not a matter of going to the doctor and getting a shot of penicillin. It's death.

Ms. TAYLOR. Unfortunately, at the moment, there is no remission.

Mr. COATS. Thank you. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Coats. Ms. Taylor, we have sent you to talk to the President. We have asked you to speak to the heads of the networks. Usually witnesses tell us what to do, and we are telling you what to do.

I think the important thing is that we need to work together, and your message to us is that we are the elected officials. The government people ought to be showing the leadership. I think, in showing leadership, we can follow your example.

Thank you very much for being with us.

Ms. TAYLOR. Thank you. Thank you very much.

Mr. WAXMAN. For our next witnesses, I would like to call forward Mr. Michael Zimmerman, Senior Associate Director, Human Resources Division, General Accounting Office, Washington, DC., accompanied by Cynthia Bascetta; Dr. Lawrence Miike, Senior Associate, Office of Technology Assessment.

We are pleased to welcome you to our hearing this afternoon. Your prepared statements we are going to make part of the record in full, but we are going to ask you to summarize or give your presentation orally in no more than 5 minutes.

We will have to be quite strict about the 5 minute rule. We are running late, and we want to give everybody the opportunity to be heard.

Mr. Zimmerman, let's start with you.

STATEMENTS OF MICHAEL ZIMMERMAN, SENIOR ASSOCIATE DIRECTOR, HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY CYNTHIA BASCETTA; AND LAWRENCE MIIKE, SENIOR ASSOCIATE-HEALTH PROGRAMS, OFFICE OF TECHNOLOGY ASSESSMENT

Mr. ZIMMERMAN. Thank you, Mr. Chairman.

I am pleased to be here today to discuss the report we issued last month, presenting the views of experts on the adequacy of the administration's proposed fiscal year 1988 budget for AIDS prevention activities. I will focus my comments today on their views, on funding education efforts to combat AIDS.

Since development of a vaccine is at least 5 years away, and probably longer, Federal, State and local health department officials and experts in the research community agree that education and prevention activities are the most powerful tools available to reduce the potential impact of the AIDS epidemic.

Overall, the experts we interviewed concurred with the priorities reflected in the administration's budget, which are: limiting the spread of AIDS among IV drug users; targeting education at high-risk groups and at the general population; and expanding voluntary counseling and testing.

The experts did not, however, agree with the proposed funding levels, and, as I will discuss, suggested that the administration's budget be substantially increased. I should add that the experts made their funding suggestions without regard to competing health priorities or Federal budgetary constraints.

The experts cited the sharing of contaminated needles by IV drug users as a dangerous and alarming problem because it represents the primary means for spreading the AIDS virus among the heterosexual population. Nationwide, 60 percent of heterosexual cases, and 73 percent of cases in newborns, were transmitted as a result of IV drug use.

The experts believe that educating IV drug users about AIDS has increased demand for methadone treatment, and that treatment can reduce the spread of AIDS by reducing the number of addicts who inject heroin. Public health officials in New York suggested an additional $50 to $150 million to expand methadone treatment in

New York City, where about one-third of the Nation's IV drug users live.

Many barriers preclude expansion of drug treatment programs, and rapid expansion over the next few years will be expensive. In the interim, less costly but also controversial methods of reducing the spread of AIDS—such as teaching drug users how to disinfect needles—can be implemented.

The experts also told us that AIDS education of the high risk groups and the general population should be pursued with a sense of urgency, and a level of funding that is appropriate for a life-or-death situation. Moreover, to limit the spread of AIDS infection, education must start or be expanded immediately in all geographic areas, including those where there are still a few cases.

According to the experts, the administration's budget request of $155 million does not provide sufficient funding for education of the general public and targeted groups. Some experts suggested that at least $100 million, in contrast to the $29 million in the administration's budget request, is needed to launch a massive public education campaign on how AIDS is spread.

They suggested using paid commercial advertising, instead of relying on public service announcements, which are generally not aired during prime viewing hours. I might add that AMA officials suggested increasing funding for AIDS education by at least $65 million more than the budget request.

Many experts expect the Federal Government to underwrite a major portion of funding for AIDS educational efforts. We believe, however, that private sector organizations, such as health and life insurance companies, have strong financial incentives to become involved in AIDS educational efforts, because they will also incur large expenses in the next few years if the AIDS epidemic goes unchecked.

I understand the hearings yesterday focused on testing and counseling. Let me add that the experts advised us that intensive educational campaigns may increase demand for testing in both high- and low-risk populations. The experts we contacted at CDC and IOM were unable to predict, however, the potential demand for testing. Thus, precise budgetary estimates are difficult to make.

Turning briefly to the cost of treating AIDS: despite widespread concerns about the financial repercussions of AIDS, data on costs of medical care, which may total $38 billion by 1991, are surprisingly scarce.

A review of cost studies done between 1985 and 1987 shows that meaningful cost comparisons are difficult to make because the studies varied in their definitions of AIDS, the types of costs included, the time periods analyzed, and the geographic areas. Estimates of individual lifetime hospital costs varied from $24,500 to $147,000, largely due to differences in lengths of hospital stays for AIDS treatment.

In summary, we believe that investing in education and prevention now can help contain the future costs of AIDS. In addition, although it is difficult to predict how the costs of treating AIDS may change over time, there is evidence that the costs per case can be minimized by delivering care outside of the hospital setting.

This concludes my statement.

[The prepared statement of Mr. Zimmerman follows:]

Statement of Michael Zimmerman

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss issues related to Federal efforts to limit the spread of Acquired Immunodeficiency Syndrome, commonly known as AIDS. My comments will primarily relate to the report[1] we issued last month on the adequacy of the administration's proposed fiscal year 1988 funding levels for AIDS prevention activities in the U.S. Public Health Service (PHS). I will also discuss the cost of caring for AIDS patients and the possible implications of alternative treatments on those costs.

My comments are based on our review of the literature and the views of our 20 experts from the research and health professional communities, advocacy groups, and State and local health departments in New York, California, Florida, Massachusetts, Illinois, and Washington, D.C. While the experts generally concurred with the prevention priorities as reflected in the budget, they told us that additional funds were needed for education, testing, and counseling services. These views are those of the individuals we contacted and not necessarily those of their affiliated organizations.

As of September 1987, over 40,000 AIDS cases had been reported to the Centers for Disease Control (CDC), up from about 300 in 1981. Most of the cases were clustered in high-incidence areas, such as New York City, San Francisco, Los Angeles, Miami, and Houston. The Public Health Service predicts that there will be a total of 270,000 cases by 1991. While San Francisco and New York currently account for over half the cases, by 1991, 80 percent of the cases are predicted to be in other areas.

The Public Health Service's budget for AIDS prevention and research has increased from $200,000 in fiscal year 1981 to over $790 million proposed by the administration for fiscal year 1988. Of this budget, about two-thirds ($519 million) would be spent on biomedical research to find a vaccine and cure. The remaining one-third ($247 million) would be used for prevention and education activities—$155 million for education ($55 million targeted at IV drug users) and $92 million for testing and counseling ($15 million targeted at IV drug users). The budget request also includes $24 million for maintaining the safety of the blood supply and other activities.

Since development of a vaccine is at least 5 years away and probably longer, Federal, State, and local health department officials and experts in the research community agree that education and prevention activities are the most powerful tools available to reduce the potential impact of the AIDS epidemic.

Overall, the experts we interviewed concurred with the priorities reflected in the administration's AIDS prevention budget for fiscal year 1988—limiting the spread of AIDS among intravenous drug users, targeting education at high-risk groups and at the general population, and expanding voluntary counseling and testing. The experts did not, however, agree with the proposed funding levels and, as I will discuss, suggested that the administration's budget be substantially increased.

The experts made their funding suggestions without regard to competing health priorities or Federal budgetary constraints. Although GAO did not develop its own funding recommendations, we offer comments that may reduce the need for Federal cost increases suggested by the experts.

The experts cited the sharing of contaminated hypodermic needles by intravenous drug users as a dangerous and alarming problem because it represents the primary means of spreading the AIDS virus among the heterosexual population. Nationwide, 60 percent of heterosexual cases and 73 percent of cases in newborns were transmitted as a result of intravenous drug use.

Methadone treatment can, the experts believe, reduce the spread of AIDS by reducing the number of addicts who inject heroin. Public health officials in New York suggested an additional $50 to $150 million to expand methadone treatment in New York City, where about one-third of the Nation's IV drug users live. Officials in Boston and San Francisco also indicated that they need additional Federal funds to expand methadone treatment, but did not cite a dollar amount.

Many social, political, and financial barriers preclude expansion of drug treatment programs and other means aimed at intravenous drug users. For example, communities often resist expansion of methadone clinics in their neighborhoods.

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[1] AIDS Prevention: Views on the Administration's Fiscal Year 1988 Budget Proposals. (GAO/HRD-87-126BR, August 12, 1987).

While drug treatment may be the preferred option, rapid expansion over the next few years will be expensive. In the interim, less costly but also controversial methods of reducing the spread of AIDS that do not involve changing drug users' basic behavior, such as teaching drug users how to disinfect needles, can be implemented.

The experts told us that AIDS education for high-risk groups and the general population should be pursued with a sense of urgency and a level of funding that is appropriate for a life-or-death situation. Moreover, to limit the spread of AIDS infection, education must start or be expanded immediately in all geographic areas, including those where there are as yet few cases. In particular, because the virus can be spread through unprotected heterosexual intercourse, the experts believe that clear and direct messages about safer sexual practices, such as using condoms, can help prevent the spread of AIDS in the general public.

According to the experts we contacted, the administration's budget request of $155 million does not provide sufficient funding for education of the general public and targeted groups. Experts from the Institute of Medicine's (IOM) Committee on a National Strategy for AIDS estimated that at least $100 milion—in contrast to the $29 million in the budget request—is needed to launch a massive public education campaign on how AIDS is spread. They suggested that the Centers for Disease Control use paid commercial advertising in prime viewing hours instead of relying on public service announcements, which are generally not aired during prime viewing hours. American Medical Association (AMA) experts suggested increasing funding for AIDS education by 3 to 5 times over the fiscal year 1987 spending level—$65 to $215 million more than the fiscal year 1988 budget request.

Many experts expect the Federal Government to underwrite a major portion of funding for educational AIDS efforts. We believe, however, that private sector organizations, such as insurance companies, have strong financial incentives to become involved in AIDS educational efforts because they will also have large outlays in the next few years if the AIDS epidemic goes unchecked. Also, the costs of the mass media campaign envisioned by the Institute of Medicine may be reduced if television and radio stations were encouraged to broadcast public service announcements during prime viewing hours as an alternative to paid advertising. Other relatively inexpensive measures, such as posting notices on public transportation, would provide a constant reminder of the threat of AIDS.

The experts expressed concern that individuals requesting testing and counseling typically had to wait several weeks to be tested. Citing unacceptable waiting periods at test sites in Chicago, for instance, the AMA recommended that testing capacity be increased by three to five times.

The populations at high risk of contracting AIDS, such as homosexual/bisexual men, IV drug users, and their sexual partners, number nearly 10 million persons, according to recent CDC estimates. At an average cost of $45 per person, potential resources needed if these individuals request testing would approach $450 million. Assuming the States match the administration's budget of about $90 million, about $250 million more in total funding would be needed to meet this demand.

Experts we contacted at CDC and IOM were unable to predict, however, the potential demand for testing from either high-risk individuals or the general public. Additional costs also would be incurred for heterosexuals who perceived themselves to be at risk for whatever reason; persons who received multiple blood transfusions in high-incidence areas before 1985; and prostitutes. Moreover, intensive educational campaigns may increase demand for testing in relatively low-risk populations. Precise budgetary needs are, therefore, difficult to estimate.

Investing in prevention now can help contain the future direct medical costs of treating AIDS. A study prepared for the Centers for Disease Control projected that treating AIDS may cost $8.5 billion in 1991 (or 1.4 percent of total personal health expenditures, up from 0.2 percent in 1985). Including the indirect costs of losses in productivity associated with premature death, these researchers predicted the total social costs of AIDS may reach $64 billion by 1991.[2] A more recent estimate of the total costs of treating AIDS predicted that cumulative medical treatment costs might reach $38 billion by 1991.[3] This study based its projections on recent research indicating that the future caseload may be greater than the Public Health Service originally predicted.

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[2] Scitovsky, Anne and Dorothy Rice. "Estimates of the Direct and Indirect Costs of Acquired Immunodeficiency Syndrome in The United States, 1985, 1986, and 1991," *Public Health Reports*, Vol. 102, No. 1, Jan.-Feb. 1987, pp. 5-16.

[3] Pascal, Anthony. *The Costs of Treating AIDS Under Medicaid, 1986-1991.* Rand Corporation, Santa Monica, Calif. May 1987.

These studies probably understate the total costs of treatment because they exclude the costs of services received outside the hospital, such as drugs, institutional or home-based long-term care, hospice care, ambulatory physician and ancillary services, and community support services. In fact, despite widespread concern about the financial repercussions of AIDS on the health care system, data on the costs for medical care of persons with AIDS are surprisingly scarce. Furthermore, no estimates are available of the costs associated with AIDS-related complex—AIDS-virus infections that do not meet the CDC definition of AIDS.

Other factors, however, may raise or lower total costs. First, the distribution of cases of AIDS and AIDS-related complex by diagnosis may change over time. For example, according to CDC, the proportion of AIDS patients with certain cancers, such as Kaposi's sarcoma, may decrease while severe lung infections, such as pneumocystis carinii pneumonia, may increase. Since the latter is more expensive to treat, direct personal medical costs would be expected to rise. Other changes in case-mix may also raise or lower total treatment costs.

Second, numerous drugs are being tested and are under development. Drugs like AZT (azidothymidine) affect treatment costs in two ways—by raising pharmaceutical costs and by changing the clinical course of the disease. Patients on this drug may live longer but require different health care services, which may in turn raise or lower costs. Moreover, drugs like AZT may improve the quality of life and decrease productivity losses if AIDS patients can continue to work longer than would have been possible without the drug. Obviously, development of a cure or vaccine will change the cost situation.

A review of cost studies done between 1985 and 1987 shows that the costs per case of treating AIDS vary significantly.[4] Meaningful cost comparisons are difficult, however, because the studies varied in their definitions of AIDS, the types of costs included, the time periods analyzed, and the geographic areas. The studies were conducted using data from New York, California, Florida, Massachusetts, Maryland, Minnesota, Alabama, and New Mexico.

Estimates of lifetime hospital costs ranged from $24,500 to $147,000. The variation is due largely to differences in lengths of hospital stays for AIDS treatment, for which there is no standard medical model. There is also some evidence suggesting that AIDS patients are now less likely to be admitted to intensive care units than they were less was known about the disease.

According to two recent articles in the *Journal of the American Medical Association*,[5] the use of inpatient hospital treatment for AIDS appears to have decreased over time. As a result, lifetime treatment costs for AIDS patients seem to have fallen. Specifically, days in the hospital from diagnosis to death fell from 168 for the first 10,000 cases [6] to 35 days (based on San Francisco data) and to 62 days (based on Massachusetts data) in 1984 and 1985.

The average length of stay is also shorter in areas where alternatives to hospitalization exist, such as outpatient diagnosis and therapy and home- and community-based services. In San Francisco, the mean length of hospital stay for all AIDS diagnoses was 11.7 days in 1984. Voluntary organizations in San Francisco provide support services to AIDS patients that allow them to leave the hospital sooner or avoid hospitalization completely. Providers in Florida also have been able to cut hospital costs by setting up outpatient treatment services for AIDS patients.

While it may be possible to increase home-based services in other communities where the caseloads are comprised of mostly homosexual men, it is more problematic in areas where intravenous drug users account for a greater percent of cases. For example, the average length of stay for AIDS patients in New York City was 50 days in 1984. This may reflect, in addition to differences in severity of illness, a lack of outpatient or home-based care for AIDS patients in New York City, of whom 30 percent are intravenous drug users.

In summary, although it is difficult to predict how the costs of treating AIDS may change over time, there is evidence that the costs per case can be minimized by delivering care outside the hospital setting. This appears to be occurring in several areas of the country.

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[4] Sisk, Jane. "The Costs of AIDS: A Review of the Estimates." *Health Affairs*, Vol. 6, No. 2, Summer 1987, pp. 5-21.

[5] Scitovsky, Anne, Mary Cline, and Philip Lee. "Medical Care Cost of Patients With AIDS in San Francisco," *Journal of The American Medical Association*, Vol. 256, No. 22, Dec. 12, 1986, pp. 3103-3106, and George Seage, *et al*, "Medical Care Costs of AIDS in Massachusetts," *Journal of The American Medical Association*, Vol. 256, No. 22, Dec. 12, 1986, pp. 3107-3109.

[6] Hardy, Ann *et al*. "The Economic Impact of the First 10,000 Cases of Acquired Immunodeficiency Syndrome in the United States." *Journal of The American Medical Association*, Vol. 255, No. 2, 1986, pp. 209-215.

This concludes my statement. I will be happy to answer any questions you may have.

Mr. WAXMAN. Thank you very much, Mr. Zimmerman.

Dr. Miike.

STATEMENT OF LAWRENCE MIIKE

Mr. MIIKE. Thank you, Mr. Chairman.

I want to congratulate you on some creative scheduling, having three Federal bureaucrats following Elizabeth Taylor. I consider that sort of a cruel and unusual punishment.

Let me just summarize some of the points that I think should be considered in a research and education bill that the Congress could support.

Number one. Two and a half years ago, we reported to this committee on the Public Health Service response, and I am glad to see the progress that has been made since that time. We really do need multi-year funding for research and education, rather than year-to-year, for better planning purposes.

One can never talk about efficiency of our research dollars because of the very nature of research; although in this area we are trying to do that with much more directed research. But it still is the bottom line that, the more money you put into a research area, the more researchers you will pull into that area. I leave that up to you, in terms of where that cut-off should be.

I also say in my testimony that one might use some construction funds creatively, as a method of bringing in new researchers, and trying to establish other than the established centers of AIDS research that exist at the present time.

Also, another one of my points is that, with this particular disease, when we develop the research agenda, we should not only pay attention to what the scientists tell us is important research, we should also be addressing public concerns. For example, earlier this month we distributed to all members of the Congress an analysis of the issue of whether insects transmit AIDS, because that was on the public consciousness. Even though scientists thought it was such a minor question, we thought that it was an important issue for the public.

Let me use an example of the kinds of areas that we need more information on that are directed at public concerns, and that's basically how the AIDS virus gets transmitted.

Simply because it's found in blood raises the question of whether mosquitoes could transmit it, and I hope our staff paper on that issue addressed that question appropriately, so one can make their own judgments on that; but my judgment is that if it ever occurs, it is going to be a very rare and unusual event, and not something that is going to be a significant contribution to AIDS transmission.

Also, the issue of saliva. We know that it can be found in small amounts in saliva, but I think it's essentially the same question as mosquito transmission. Simply because one finds it in a particular body fluid doesn't mean AIDS can be transmitted that way, the conditions have to be right before transmission can occur in that fashion.

Another area that I think we need to get into and which touches directly on the testing issue is that we need better tests for infection. Recently, actually this morning, I gave a little talk about the accuracy of the AIDS antibody test, and everybody assumes that with what everybody now hears about the ELISA and the Western Blots, that everything is hunky-dory.

I want you to know that there is no standard for what is a positive Western Blot, and really the Department of Defense interpretation of a positive Western Blot is quite different from the Red Cross's interpretation of a Western Blot, and I am a little worried that significant numbers of the military people who have been identified through ELISA's and Western Blots as HIV positive may, in fact, not be infected with the virus. So I think we need better tests on who is infected or not.

And finally all of these kinds of information tie into the educational campaign area. We really need to find better ways of communicating what are really probability estimates from research and translate that into language that the public can understand and can make their own judgments about risk.

One other area for educational strategies, I think, is that we should—it brings to mind in the early 1970's our attempts to make physicians more compassionate and get them more into general practice and family practice rather than into the specialties. I think a similar effort is needed in our health profession schools to educate students now, so that they can be compassionate toward AIDS patients and don't turn away from them as they get into practice.

[The prepared statement of Mr. Miike follows:]

Statement of Lawrence Miike

I am Dr. Lawrence Miike, Senior Associate in the Health Program of the Office of Technology Assessment (OTA), and I am here today to comment on Federal support for research and education on AIDS.

Among the AIDS-related activities at OTA is a series of staff papers, initiated in June of this year at the suggestion of OTA's Congressional Board and with the encouragement of the House Appropriations Committee. The first staff paper, *Do Insects Transmit AIDS?*, was released earlier this month. We expect to issue a second staff paper, on the cost-effectiveness of preventive education programs, in early 1988.

OTA first reported to this subcommittee on the Public Health Service's (PHS) response to AIDS in February 1985. At that time, our conclusions were as follows:

OTA concludes that although PHS has indeed undertaken a massive effort and made significant accomplishments, the statement that AIDS is DHHS's number one health priority has not always been supported by financial and personnel resources. The responsibility for this situation, however, appears not to rest with the Office of the Assistant Secretary in PHS, but instead reflects decisions made at higher levels of the Federal Government. The administration has not pursued an appropriation for the Public Health Emergency Act, choosing instead to rely on securing appropriations for individual PHS agencies from Congress. Although sufficient and uncertain distribution of resources has not been the sole cause of delays or inadequacies in PHS AIDS research, surveillance, and service provision, it has resulted in at least inadequate planning, increased competitiveness among Agencies, inadequate attention to certain areas which are perceived by many to be important (e.g., public education and prevention), and a diversion of attention from other critical health areas.

Although significant advances have been made in understanding AIDS, its primary cause, and associated factors, it will be some time before this biomedical knowledge can be expected to be translated into effective preventive and therapeutic interventions. In the interim, and probably even if biological remedies become available, prevention through education on ways of minimizing exposure to HTLV-

III (the current name for the AIDS virus is HIV, for "human immunodeficiency virus") has the greatest potential of limiting the spread of AIDS. So far, efforts to prevent AIDS through education have received minimal funding, especially efforts targeted at the groups at highest risk.

In testimony before this subcommittee when OTA delivered its report, we emphasized the importance of preventive education:

Up to this time, the major emphasis of the Federal Government's AIDS activities has been to seek a technological solution—to find the biological cause of AIDS, to develop effective drugs against the disease, and to develop a vaccine if possible. These efforts are as important now as when they were first formulated, but it has also become obvious that a quick technological solution is not at hand and that progress against AIDS will come in increments. Thus, to minimize the spread of AIDS, non-technological approaches also need more emphasis than they have received so far, such as educating persons at risk on how they can avoid being exposed to the AIDS virus.

In the interval since we testified before this subcommittee in February 1985, tests to identify persons with antibodies to the AIDS virus (and presumed to be carriers of the AIDS virus) have become available and are widely used, and the first drug against the AIDS virus itself (azidothymidine or AZT, now called zidovudine, trade name Retrovir®) is now available. However, the availability of the AIDS antibody test has brought the issue of mandatory versus voluntary testing to the fore, and treatment with AZT has turned out to be unexpectedly costly (about $10,000 per patient per year). Moreover, there is still wrangling over how to implement preventive strategies and how much to invest in these activities.

Finally, we made the following observation in February 1985:

If we are in for a prolonged battle against AIDS, then we must begin to think of strategies other than the one currently being followed. Currently, support for AIDS activities has been formulated on a year-to-year basis, and the Federal emphasis has been on developing methods to diagnose, prevent, and treat the disease. The tension among the individual PHS agencies, DHHS, and the Congress has stemmed largely from differences over the source of funds for AIDS activities and on the amount of funds that should be devoted to AIDS. The Department prefers to reallocate PHS agency funds from other activities to AIDS; and even when Congress has earmarked specific amounts for AIDS, the Department has at times ended up obligating more than these earmarked amounts to AIDS.

The question is whether or not such reallocation and year-to-year funding will be sufficient in the future. General budgetary constraints mean that PHS agencies will be even more pressed to decrease their overall funding and staffing levels at the same time that the AIDS problem continues to increase. Should we begin to think of funding AIDS activities on a long-term basis, with multi-year instead of year-to-year budgeting? Is AIDS such a grave public health problem that it should be excepted from the general budgetary constraints that are being imposed on the PHS and government programs in general? Should legislation be enacted with a special budget for AIDS?

Such legislation is now under consideration in the House and Senate, and reports by the Institute of Medicine and the General Accounting Office have emphasized the importance of preventive education.

Now, let me make some further suggestions for Federal support for research and education. First, enlarging the AIDS research budget will of itself bring in additional researchers into the AIDS area. In addition, efforts to bring in younger researchers traditionally take place through training grants or through "new investigator" awards. However, these grants/contracts usually are awarded through centers already known for their excellence. Facilities construction funds could be used to develop additional ways of infusing new blood into AIDS research. For example, some construction funds could be set aside to build containment facilities (i.e., facilities that are necessary for laboratory work with the AIDS virus) so that more research centers could devote work to AIDS.

Second, more research needs to be conducted on the ways in which infection with the AIDS virus is transmitted. It is not enough to say, for example, that kissing and spitting cannot transmit the virus, even though scientists have found small amounts of the virus in saliva.

Third, it is obvious that AIDS is of great concern to the public at large, and not only to the research and medical communities. Thus, public concerns and fears must somehow also be included in the criteria that funding Agencies develop when planning their AIDS research agendas. The issue of how infections with the AIDS virus can be transmitted is the foremost area of research that would be affected. Recently, OTA decided to address the issue of whether insects are transmitting the

AIDS virus. We were questioned by some in the research community as to why we chose to address the issue, since in their opinion, it was a very minor question. But it is a major issue for the public, and we chose to attempt to provide objective information on the question instead of leaving it up to unsupported allegations as the primary means of "informing" the public.

Fourth, we need better means of communicating research findings to the public, despite the difficulties of doing so when much of the public want absolute answers and the media is eager to report on any new twist to the AIDS epidemic.

Fifth, we need to inform health care workers on AIDS before they are faced with the actual care of AIDS patients, and we need to infuse compassion, understanding, and a commitment to the care of AIDS patients in our future physicians and other health workers. In the early 1970's, attempts were made to develop a commitment toward primary care among medical students. Similar commitments are now needed toward the care of AIDS patients.

Mr. Chairman, that completes my prepared testimony, and I would be happy to answer any questions you or other members of the subcommittee might have.

Mr. WAXMAN. Thank you very much, Dr. Miike.

Mr. Zimmerman, the experts whom you contacted said that the current budgets for information and education were inadequate. The National Academy of Sciences, for instance, suggested that the budget for public education should be more than tripled.

Did anyone argue that the education effort currently planned will be adequate?

Mr. ZIMMERMAN. No, sir, none of the experts that we contacted took such a position.

Mr. WAXMAN. Did most of the experts agree that mass media public education is necessary and appropriate?

Mr. ZIMMERMAN. Yes, sir.

Mr. WAXMAN. Did you discuss with these experts the different efforts that may be needed for different audiences, say school education or drug addict education or education of gay men?

Mr. ZIMMERMAN. They discussed with us that point rather emphatically. Just about every group we contacted had a view that the media campaigns have to be tailored to the particular groups and the types of persons that you're trying to reach.

Mr. WAXMAN. You have suggested that some of the mass media work might be done by urging the networks to donate public service announcements. Has this happened during prime time, and isn't prime time usually reserved for paid advertising?

Mr. ZIMMERMAN. That's correct, but I thought your conversation earlier today would be a good start. It seems to me that some type of pressure has to be put on the media to join in and help.

Mr. WAXMAN. You suggested that some of the education work on AIDS might be done by insurance companies. You say, however, that the experts you spoke to suggested multi-million-dollar budgets. I know that the insurance industry has done some work. But do you believe that they will donate the $30 million needed for a house-to-house mailing or the $100 million needed for widespread TV advertising?

Mr. ZIMMERMAN. I don't think they'll donate that much, but they are clearly concerned about it. And as the epidemic spreads, I think their concern is going to heighten, and I think you're going to see more participation, although I don't think it will be widespread by the insurance industry.

Just last week, Metropolitan Insurance Company ran or sponsored a show—I don't know what it cost them, but it clearly wasn't for nothing—it was an hour of prime time TV, and I think other insurance companies, particularly life insurance companies that are at high financial risk, I think they're going to take part.

I also think State and local governments have a responsibility, too, though a lot of their money is Federal money. Nevertheless, I think they ought to take the lead, particularly communities that are hard hit now. I'm quite sure they are spending money, and I expect others to join in.

Mr. WAXMAN. One observation I would make as someone who has been involved as a Congressman in this AIDS issue since 1981 is that all of these groups that stand to lose so much money financially—the insurance industry, the health industry, and all its components—have not come to us and insisted that we appropriate the funds for research, appropriate the funds for education. They have been standing on the sidelines until very recently, and it as been small groups like the gay men's groups that have come in, seeing their own dying from AIDS, pleading that we do what we're now finally seeing everybody agree that we should have been doing for some time.

Your point is well taken. They do have a clear financial incentive to want to have educational efforts succeed. Now whether some of these industry groups will back that up and take some leadership is an open question in my mind.

Mr. ZIMMERMAN. To some degree, it is in mine, too, to be frank with you.

Mr. WAXMAN. Mr. Dannemeyer.

Mr. DANNEMEYER. Mr. Zimmerman, have either you or Dr. Miike produced any estimates of the numbers of people in America today that have the virus?

Mr. ZIMMERMAN. We haven't. At the GAO——

Mr. MIIKE. There are some attempts, and it's really more or less on a theoretical basis on what kinds of models one might develop in the absence of good, broad data. So that's still an open question.

Mr. DANNEMEYER. One rule of thumb that's been articulated is that if you multiply the number of people with fully developed AIDS, currently 41,000 plus, by 100, we'd have a rough analysis of the number of people in this country with the virus.

Do you believe that's a correct assessment?

Mr. MIIKE. In terms of ballpark figures, I would say that might be a little bit overestimated, if you're talking about 100 to 1. But I'm really not the person to answer that question, because if we're talking about a conversion rate anywhere between 20 and 60 percent, it doesn't seem to match. You talk about an AIDS case with 99 others.

But on the other hand, the numbers that we've heard, which is about 1.5 to 2 million, have not changed over the past 2 years, and we know that it has to change.

Mr. DANNEMEYER. What did you say? A conversion rate of what?

Mr. MIIKE. Well, the current estimates about people who go on from infection to frank disease, AIDS, now range anywhere from 20 to 60 percent over a 5- to 10-year period.

Mr. DANNEMEYER. Well, you're speaking about what we heard, what we were told 6 months ago. The current estimates that I have seen is that it will be 70 to 80 percent of the virus will go on to develop frank AIDS.

Mr. **Miike**. One has to understand that those are based on very small numbers of people followed—you know, we're talking about maybe a few hundred people followed for a length of time, and so estimates are made based on whatever evidence is available.

Mr. **Dannemeyer**. Also we've heard estimates that the quantity of people that have ARC today, not yet fully developed AIDS, is roughly a factor of 10 times the number who have fully developed AIDS. Do you think that's a fair estimate?

Mr. **Miike**. No. I think that's an overestimate.

Mr. **Dannemeyer**. Pardon me?

Mr. **Miike**. I think that's an overestimate.

Mr. **Dannemeyer**. An overestimate?

Mr. **Miike**. I think that's an overestimate. But it also again gets into definitional questions about what is ARC.

Mr. **Dannemeyer**. Don't you think it would be good public policy for our public health authorities at the Federal and State levels to have a better knowledge of the people in the country that have the virus?

Mr. **Miike**. Definitely. However, I think the basic issue, which you are well familiar with, is how to get that information and who to test.

Mr. **Dannemeyer**. Well, do you believe, therefore, that public policy would require that we begin testing people in certain groups in order to find out how many of the American people have the virus?

Mr. **Miike**. It would depend on who we would test, and I think that——

Mr. **Dannemeyer**. Well, let me give you an example. Hospital admittees between the age of 14 and 49, persons convicted of drug abuse or prostitution, persons visiting STD clinics, persons entering the prison population, persons applying for marriage licenses.

It's been estimated that these groups would include roughly 50 million people. Do you believe it's sound public policy to test people in those groups in order that we have a better understanding of the number of people with the virus?

Mr. **Miike**. Well, my personal opinion is that I might agree with testing some of those people, but in terms of blanket testing of categorical groups, I have some problems with that.

And, Congressman Dannemeyer, I'm not talking simply about the civil rights aspects, but I'm talking about the rate of return and the issue of the number of people who would be falsely identified, even after confirmatory testing. And I can submit some information to you later for the record that would outline why my concerns are in that area, in testing low-incidence people.

Mr. **Dannemeyer**. Well, you're familiar, of course, with the fact that the ELISA test if normally used and if positive, is then confirmed, and then a third test, the Western Blot. Are you familiar with that?

Mr. **Miike**. Yes. But if you notice, when I gave my oral statement, there is no standard for the Western Blot. The Defense Department uses different criteria from the Red Cross, and I can give you some examples. If we're talking about a population—suppose we test 100,000 people. Suppose the prevalence of HIV infection is 0.01 percent. We have a test, the ELISA test, that's now 100 percent sensitive, meaning it would pick up everybody who would be infected, and a specificity of 99 percent, meaning only 1 percent false positives. Even after the Western Blot, which itself has a false positive rate of 1 percent, one would find in that 100,000 people 20 positives, 10 of which would be falsely accused of being HIV positive.

Mr. DANNEMEYER. Well, I see my time has expired. I have some other questions. Perhaps we'll have another round.

Mr. WAXMAN. Without objection, the gentleman might take an additional minute, because I'd like to not go for another round.

Mr. DANNEMEYER. Have you estimated what it costs for each of these persons who have fully developed AIDS for health care costs?

Mr. ZIMMERMAN. We have no estimates of what it costs. Studies have been done of past cost experiences, and it ranges from $25,000 say, to $150,000.

Mr. DANNEMEYER. Per patient?

Mr. ZIMMERMAN. Per patient.

Mr. DANNEMEYER. And based on your analysis, what do you estimate the cost to the health care system for caring for patients—persons with AIDS, not ARC, not the virus, just AIDS in the next 4 or 5 years?

Mr. ZIMMERMAN. Well, I think the most recent study was done by the Rand Corporation. Let me say first that the GAO has not done a study of the overall cost of AIDS, particularly one over a period of 4 or 5 years. Maybe Ms. Bascetta can respond to the cost data.

Ms. BASCETTA. The most recent data that the CDC have estimates that direct medical care costs will approach $8.5 billion in 1991, and that——

Mr. DANNEMEYER. In that year?

Ms. BASCETTA. In 1991. And that including the indirect cost, the productivity losses associated with those cases of AIDS in 1991, total social costs will be approximately $64 billion.

Another study that the Rand Corporation did, which used a slightly greater caseload projection for 1991, estimated medical care costs of $38 billion in 1991.

Mr. MIIKE. Congressman Dannemeyer, may I add to that?

Mr. DANNEMEYER. Yes.

Mr. MIIKE. Secretary Bowen estimates that next year Medicare costs—Medicaid costs, I'm sorry—for treatment of AIDS patients will be about $600 million with another $75 million for AZT. And if you figure that Medicaid costs are approximately about 40 percent of the total cost, then were talking about $1.5 billion next year, direct medical costs.

Mr. DANNEMEYER. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Dannemeyer.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Miike, do I understand from your testimony that you believe renovation and construction money are necessary new expenses for AIDS research?

Mr. MIIKE. I'm sorry. Would you rephrase that again?

Mr. Wyden. Is it your testimony that renovation and construction money are needed new expenses for AIDS research?

Mr. Miike. What I suggested is that in addition to grants and contracts to individual researchers and research projects, that one way of trying to build a cadre of AIDS researchers, in addition to the traditional method of training grants and new investigator grants, is, for example, one might build a modest amount of containment facilities, so that different centers can do AIDS research who are not able to do it now.

Mr. Wyden. I understand in your testimony, that you believe that fellowship and training money for young investigators are much needed investments in the AIDS research field.

Could you elaborate a little bit on why that is the case?

Mr. Miike. Well, I guess one of the issues in the AIDS area is long-standing—the peer review process, who gets grants and contracts, and one way to bring in new people who have no track record in a particular area of research is traditionally to go through the training grants to build up the cadre of people. And anyone who has followed the training grant and fellowship programs as part of the research establishment, that's always been the orphan in the research area. And I think that if we're looking long-term, one has to build up both facilities and people in the AIDS area.

Mr. Wyden. The theory is that you have to round up people into the field and not incessantly overwork the people who are already in the field.

Mr. Zimmerman. Mr. Wyden, may I just comment on the question of construction of facilities?

In our contacts with the experts, particularly the ones that were affiliated with the Institute of Medicine study and also at hearings we've participated in in Florida last month, there was much discussion of the need for expanded research facilities.

The amount of moneys that were presented, for example, by the Institute experts didn't seem to be overwhelming, somewhere in the neighborhood of $20 million, but they felt it was very essential if the research activities are going to go forward like they should. Without the right facilities, they felt they couldn't achieve the objectives that they want to achieve.

Mr. Wyden. Well, I commend all of you for a very excellent job and an important contribution.

Thank you, Mr. Chairman.

Mr. Waxman. Thank you, Mr. Wyden.

Thank you both, all three of you, for your testimony and your work on this issue. It's been very helpful to us.

[Testimony resumes on p. 208.]

[The following information was submitted for the record:]

HOW ACCURATE IS AIDS ANTIBODY TESTING?

Lawrence Miike, Senior Associate
Office of Technology Assessment
U.S. Congress

Description of the Tests

Tests to detect antibodies to the AIDS virus (HIV, for "human immunodeficiency virus") in blood consist of two types of tests applied in sequential order to the same blood specimen. If the first test is positive, it is repeated. If the repeat test is again positive, then the second test is performed. Testing is not repeated on specimens that are negative on the first test, nor is the second confirmatory test performed on initially negative specimens.

The first tests are enzyme immunoassays (EIAs), in which antibodies to whole and partial virus are measured in the aggregate. The second, more specific test, called a "Western blot," identifies antibodies to the major individual proteins which make up the AIDS virus.

Most of the EIAs are "ELISA" (enzyme-linked immunosorbent assay) assays. Here, serum is placed in wells or on beads that contain HIV antigen (derived from disrupted HIV that has been grown in cell cultures). If the specimen contains antibodies, they will bind to the test kit's antigens. After an incubation period, any unbound antibody is washed from the bead or well, and an enzyme-labeled antibody to human immunoglobulin (all antibodies are immunoglobulins) is added. The bead or well is again washed to remove any unbound antibody. A reagent is then added that will react with any bound, enzyme-labeled antibodies, and the reaction produces a color change that is measured by an instrument called a "spectrophotometer." The color intensity is quantifiable and the numerical value is called the "optical density." The result is interpreted by comparing it to positive and negative control samples containing known quantities of antibodies.

There are also competitive EIAs, in which enzyme-linked antibodies to HIV are added to the well containing HIV antigens at the same time as--instead of after--the test specimen. If the specimen contains antibodies to HIV, they will compete with the test kit antibodies in binding with the HIV antigens. If there is a lot of antibodies to HIV in the specimen, there will be little enzyme-linked antibodies found bound to the HIV antigens. If the specimen contains no antibodies to HIV, all bound antibodies will be the enzyme-linked antibodies from the test kit.

Western blot testing is based on identifying antibodies to the major proteins of the AIDS virus. Purified HIV antigens are separated electrophoretically on a gel, which results in their separation by their molecular weights. They are then blotted onto special paper. A sample of serum is applied to the paper and if antibodies to HIV are present, they will bind to the viral antigens. A radioactive- or enzyme-labeled antibody to immunoglobulin is then applied to the paper. If antibodies to HIV are present in the sample and have bound to the HIV antigens, they will appear as distinctive bands on the blot. The location of the band indicates reaction to a specific viral protein (See bands depicting the "positive control" specimen in figure 1).

HIV proteins are grouped into three classes, two structural and one regulatory. The structural proteins consist of: 1) proteins that provide the internal, or "core" (also known as "gag") structure of the virus, and 2) proteins that provide the external or "envelope" (also known as "env") structure of the virus. The regulatory proteins (also known as "pol") represent the regulatory enzymes (reverse transcriptase, endonuclease) of the virus. Envelope proteins also have non-protein elements (glycogen) incorporated into them. The core proteins include p17/18, p24/25, and p55, which are shorthand designations for proteins with molecular weights in the thousands (or "kilodaltons"). Thus, "p24/25" refers to a protein with a molecular weight of 24 to 25 thousand. The envelope proteins are gp41, gp110/120, and gp160, where "gp" refers to "glycoprotein" (the first vaccine undergoing preliminary testing produces antibodies against gp120). The regulatory proteins are p31/32, p51/53, and p65/66.

Accuracy of the Tests

When performed in the best laboratories, the tests are very accurate. One estimate is that the false positive rate after both ELISA and Western blot testing is only 1 in 20,000 specimens tested (0.005 percent false positive rate).[1] This is based on the assumptions: 1) that the EIA test is 100% sensitive (i.e., that it will identify all antibody-positive blood specimens)[2] and 99.6% specific (i.e., that of 1,000 antibody-negative blood specimens, only 4 will be identified as positive for antibodies to HIV), and 2) that when EIA-positive blood specimens are tested by Western blot, the false-positive rate for the Western blot test is 1.17%. Multiplying the false-positive rate for the EIA test (0.4%) by the false-positive rate for the Western blot (1.17%) results in a joint false-positive rate of 0.005% (0.004 x 0.0117 = 0.0000468 = 0.005%).

One study of six commercially available EIA tests used to test blood donors found a false positive rate of zero to 0.42 percent.[3] However, there can be variations in the false positive rates for the EIA tests, even among different batches of one manufacturer's test kit,[4] and the false positive rate of the EIA test can be as high as 6.8 percent among hospitalized patients.[5] Thus, a false positive rate of 0.4% for the EIA test represents a best-case scenario.

The 1.17% false positive rate for specimens that were repeatedly positive on EIA testing and then subjected to Western blot testing comes from a U.S. Army study.[6] Only specimens that are repeatedly positive on the EIA test are subjected to Western blot testing, so labs perform the Western blot test on specimens that they know are already presumed to be positive. The false positive rate might be higher if specimens that were negative were also tested by Western blot; i.e., if laboratory personnel conducted the Western blot test on specimens that the labs did not know were positive or negative on EIA testing. For example, as part of the U.S. Army's quality assurance program for AIDS antibody testing, five large commercial laboratories that offered Western blot testing on a fee-for-service basis were sent 15 samples that were known to be negative for antibodies to the AIDS virus, and 5 samples that were positive. There were six false-positive results reported, all on different normal specimens, suggesting that the errors were due to technique. The most common error was detection only of p24/25, and labeling that result as a positive Western blot test. Four of the five laboratories reported at least one false-positive test result. One laboratory did not detect one of the positive specimens.[7]

False positive Western blot tests have resulted from reactivity to the cultured human cells in which the AIDS virus that is used in Western blot testing has been grown.[8] For example, the American Red Cross reports that Western blot testing on specimens that are positive with Abbott's EIA test result in "indeterminate" readings 10 to 20 percent of the time, while Western blot testing on specimens that are positive with Genetic Systems' or DuPont's

EIA tests results in "indeterminate" Western blot readings 40 to 50 percent of the time.[9] Furthermore, subsequent blood apecimens obtained from the same patient can be Western blot negative after an initial specimen was Western blot positive.[10]

The Centers for Disease Control (CDC) has estimated that currently licensed EIA tests have a sensitivity of 99 percent or greater and a specificity of approximately 99 percent.[11] The CDC also states that the sensitivity of the Western blot is comparable to that of the EIA. While no specificity is given for the Western blot (described as "highly specific when strict criteria are used for interpretation"), CDC does state that: "Under ideal circumstances, the probability that a testing sequence will be falsely positive in a population with a low rate of infection ranges from less than 1 in 100,000 (Minnesota Department of Health, unpublished data) to an estimated 5 in 100,000 (citing as references Meyer and Pauker and Burke et al., see footnotes 1 and 6, supra)."

There is at present no standard for determining when a Western blot test is positive. A Consensus Conference from the Office of Medical Applications of Research, National Institutes of Health, stated that p24/25 together with gp41 (a "gag" protein and an "env" protein) "is unequivocally positive."[12] The Department of Defense (DoD), in its mandatory testing of active duty personnel and civilian applicants for U.S. military service, classifies as positive those Western blot tests in which, at the minimum, either gp41 (an "env" protein) alone or p24/25 plus p55 (two "gag" proteins) are detected.[13] The American Red Cross requires that at least one protein from each of the three types of proteins ("gag," "pol," and "env")--for example, p24/25 plus gp41 plus p51/53--be detected before the donor is notified that he/she has been found to be positive for antibodies to the AIDS virus.[14]

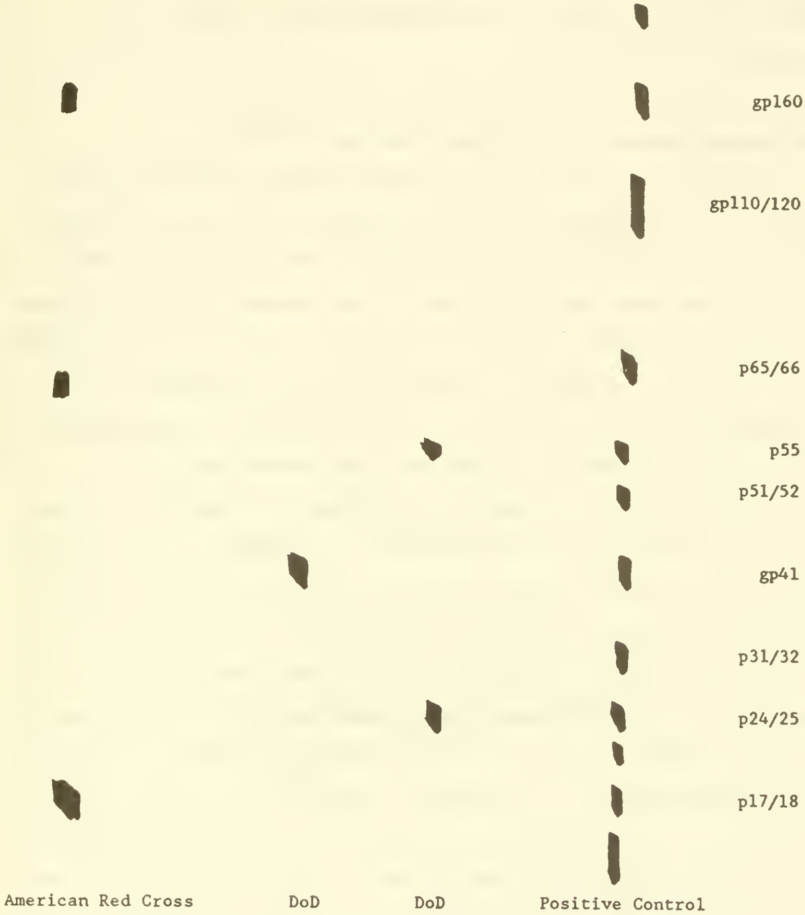
The Red Cross standard applies only to whether the blood donor will be notified that he/she has had a positive antibody test to HIV. All repeatedly positive EIAs are discarded, regardless of the results of Western blot testing. If some antibodies to HIV antigens are detected but not against at least one protein from each of the three types of HIV antigens, the results are reported to the blood bank as "indeterminate" (all of these specimens are also discarded, because all repeatedly positive EIAs are discarded, and only repeatedly positive EIAs are subjected to Western blot testing). The individual blood banks determine whether to inform persons with indeterminate Western blots of their test results. Indeterminate Western blots that contain antibodies to p24/25 and gp160 are tagged as probably representing the early stages of conversion to positive antibody status. Approximately 80 percent of persons with this Western blot pattern have progressed to positive Western blots as defined by the American Red Cross.

In reference to the NIH Consensus Conference definition that a positive Western blot consists of p24/25 plus gp41, and the DoD definition of either gp41 alone or p24/25 plus p55, there may not be that much difference in results. The American Red Cross reports that it is very unusual to find only these minimal types of proteins on the Western blot test. Nevertheless, American Red Cross and the Department of Defense have clearly different criteria for when a person will be labeled as being infected with HIV and being informed of the results, and research studies often use yet another criterion, the NIH Consensus Conference definition, for a positive Western blot (i.e., p24/25 plus gp41).[15]

Figure 1 depicts a hypothetical situation involving three persons, two of which would be identified as having a positive Western blot by DoD and one of which would be identified as positive by the American Red Cross. In this

Figure 1

Western Blot: Hypothetical Situation In Which American Red Cross And Department Of Defense Criteria For A Positive Test May Differ[1]



[1] See text for explanatory details

hypothetical situation, note that: 1) neither of the DoD positives would be identified as positive by the American Red Cross, 2) the Red Cross positive would be negative by DoD criteria, and 3) neither the Red Cross nor DoD positives would be identified as positive according to the NIH Consensus Conference definition.

Test Accuracy Depends On The Population Undergoing Testing

Even when the tests are conducted under optimal laboratory conditions, there will be antibody-positive persons who will be missed, and some persons who will be incorrectly identified and hence, assumed to be infected and carriers of the AIDS virus. Furthermore, among persons identified as having antibodies to the AIDS virus, the proportion of incorrectly identified persons (i.e., the percent of false positives) will increase as the prevalence of antibody-positive persons among the population undergoing testing decreases. These unavoidable errors are illustrated in the accompanying figures.

In figure 2, the relationship between sensitivity, specificity, false negatives, and false positives are summarized. In figures 3 to 6, the false positive rates after both EIA and Western blot testing are calculated for populations where the prevalences of antibodies to the AIDS virus are 10 percent, 0.83 percent, 0.1 percent, and 0.01 percent, respectively. A population with 10 percent prevalence of antibodies to HIV would represent a high-risk population. The 0.83 percent prevalence represents the threshold for mandatory marriage license applicant testing under a law passed in Texas in 1987,[16] and is the prevalence obtained if the 2 million persons estimated to be infected with HIV in the United States is divided by 240 million, the current estimated population of the U.S. The 0.1 percent represents the

Figure 2

Sensitivity, Specificity, and Predictive Value of Testing

ANTIBODIES

		Present	Absent
Test	Positive	A = True Positive	B = False Positive
	Negative	C = False Negative	D = True Negative

Sensitivity = A/(A + C)

Specificity = D/(B + D)

Predictive Value Of A Positive Result, Or
Probability That A Positive Result Is Correct
= A/(A + B)

prevalence of HIV infection that CDC has suggested may justify premarital testing (see footnote 11, supra). The 0.01 percent might represent the prevalence rate in low-risk groups.

In these examples, CDC estimates (see above) of the sensitivity and specificity of the EIA and Western blot tests have been used. For the EIA test, sensitivity and specificity are both assumed to be 99 percent (1 percent false negatives, 1 percent false positives). For the Western blot, sensitivity is assumed to be 99 percent, and specificity, from 99.5 to 99.9 percent. The false negative rate after both EIA and Western blot testing is 2 percent and is derived by adding the false negative rates for each test, because Western blot testing is done only on specimens that test positive. After EIA testing, 1 percent of positive specimens will be missed (0.01 x (# of positive specimens)). Western blot testing of EIA-positive specimens will miss 1 percent of these specimens, or approximately an additional 1 percent of the total number of positive specimens (0.01 x 0.99 x (# of positive specimens) = 0.0099 x (# of positive specimens)).

The false positive rate after both EIA and Western blot testing is derived by multiplying the false positive rates for EIA and Western blot testing, because Western blot testing is conducted only on those negative specimens that tested falsely positive on EIA. If the joint false positive rate is 1 in 100,000 (0.00001) to 5 in 100,000 (0.00005) and the EIA false positive rate is 1 percent (0.01), the false positive rate for the Western blot therefore ranges from 0.001 to 0.005, or 0.1 to 0.5 percent (0.01 x (0.001 to 0.005) = 0.00001 to 0.00005), or 1 in 100,000 to 5 in 100,000).

The examples all assume that 100,000 persons are being tested. For the group with 10 percent of its members having antibodies to HIV in their blood, an EIA test sensitivity of 99 percent means that, of 10,000 antibody-positive persons, 9,900 will test positive (true positive), and 100 will test negative (false negative). Of the 90,000 persons without antibodies to HIV, an EIA test with a specificity of 99 percent means that 89,100 will test negative (true negative) and 900 will test positive (false positive). The predictive value of a positive EIA test is thus 9,900 divided by 9,900 plus 900, or 92 percent; i.e., after only EIA testing, the probability that a positive result is truly positive is 0.92.

The results after Western blot testing are as follows. A test sensitivity of 99 percent means that, of the 9,900 persons testing positive after EIA testing and who actually have antibodies to HIV present, 9,900 x 0.99, or 9,801 persons will be correctly identified as positive, and 99 persons will be incorrectly identified as being antibody-negative. Therefore, after both EIA and Western blot testing, a total of 100 plus 99 antibody-positive persons, or 199 of 10,000, will be missed. Western blot specificity of 99.5 to 99.9 percent means that, of the 900 persons without antibodies that were falsely positive in the EIA test, 0.1 to 0.5 percent will still be falsely positive after Western blot testing, or a total of 1 to 5 persons. Therefore, of the 90,000 antibody-negative persons, 1 to 5 persons will be falsely identified as positive, compared to 9,801 persons correctly identified as antibody positive. The predictive value after both EIA and Western blot testing ranges from 9,801/(9,801 + 5) to 9,801/(9,801 + 1), or from 99.95 to 99.99 percent, as compared to a predictive value of 0.92 after only EIA testing (see figure 3 for summary).

Similar computations have been made for populations of 100,000 each, with prevalence rates of antibodies to HIV of 0.83, 0.1, and 0.01 percent, respectively.

Figure 3

Predictive Value. 10 Percent Prevalence[1]

		Antibodies	
		Present	Absent
EIA	Positive	9,900	900
	Negative	100	89,100

		Present	Absent
Western blot	Positive	9,801	1-5
	Negative	99	895-899
		9,900	900

Predictive Value of EIA = 9,900/(9,900 + 900) = 0.92

Predictive Value of EIA plus Western blot =
9,801/(9,801 + 5) to 9,801/(9,801 + 1) = 0.9995 to 0.9999

Number of False Negatives =
100 + 99 = 199

Number of False Positives =
900 x (0.001 to 0.005) = 1 to 5

Number of True Positives =
10,000 minus 199 = 9,801

[1] See text for assumptions

In the 0.83 percent prevalence group, the probability of a positive test being correct after EIA testing would be only 0.45, but would rise to 0.994 to 0.999 after Western blot testing (814/819 to 814/815). Sixteen of 830 antibody-positive specimens would be missed. As in the case of the 10 percent antibody-positive prevalence population, 1 to 5 persons would be incorrectly identified as antibody positive, compared to 814 persons correctly identified as antibody positive (see figure 4 for summary).

In the 0.1 percent prevalence group, the probability of a positive test being correct after EIA testing would be only 0.09, but would rise to 0.951 to 0.990 after Western blot testing (98/(98 + 5) to 98/(98 + 1). Two of 100 antibody-positive specimens would be missed. One to 5 persons would again be incorrectly identified as antibody positive, but at a prevalence of 0.1 percent, only 98 persons will be correctly identified as antibody positive (see figure 5 for summary).

In the 0.01 percent prevalence group, the probability of a positive test being correct after EIA testing would be only 0.01, rising to 0.667 to 0.909 after Western blot testing (10/(10 + 5) to 10/(10 + 1). All 10 of the antibody-positive persons would be identified. One to 5 persons would again be incorrectly identified as antibody positive, but only 10 persons will be correctly identified as antibody positive, even though no positives will be missed (see figure 6 for summary).

In summary, the percent of false negatives and false positives will be identical in populations with different prevalences of antibody-positive persons. However, in higher prevalence populations, the absolute number of antibody-positive persons who will be missed (false negatives) after both EIA and Western blot testing will be much higher than in lower prevalence populations. For example, among 100,000 persons tested, 199 of 10,000

Figure 4

Predictive Value, 0.83 Percent Prevalence[1]

		Antibodies	
		Present	Absent
EIA	Positive	822	992
	Negative	8	98,178

		Present	Absent
Western blot	Positive	814	1-5
	Negative	8	987-991
		822	992

Predictive Value of EIA - 822/(822 + 992) - 0.45

Predictive Value of EIA plus Western blot -
814/(814 + 5) to 814/(814 + 1) - 0.994 to 0.999

Number of False Negatives -
8 + 8 - 16

Number of False Positives -
992 x (0.001 to 0.005) - 1 to 5

Number of True Positives -
830 minus 16 - 814

[1] See text for assumptions

Figure 5

Predictive Value, 0.1 Percent Prevalence[1]

		Antibodies	
		Present	Absent
EIA	Positive	99	999
	Negative	1	98,901

		Present	Absent
Western blot	Positive	98	1-5
	Negative	1	994-998
		99	999

Predictive Value of EIA = 99/(99 + 999) = 0.09

Predictive Value of EIA plus Western blot =
98/(98 + 5) to 98/(98 + 1) = 0.951 to 0.990

Number of False Negatives =
1 + 1 = 2

Number of False Positives =
999 x (0.001 to 0.005) = 1 to 5

Number of True Positives =
100 minus 2 = 98

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[1] See text for assumptions

Figure 6

Predictive Value, 0.01 Percent Prevalence[1]

		Antibodies	
		Present	Absent
EIA	Positive	10	1,000
	Negative	0	98,990

		Present	Absent
Western blot	Positive	10	1-5
	Negative	0	995-999
		10	1,000

Predictive Value of EIA - 10/(10 + 1,000) - 0.01

Predictive Value of EIA plus Western blot -
10/(10 + 5) to 10/(10 + 1) - 0.667 to 0.909

Number of False Negatives -
0 + 0 - 0

Number of False Positives -
1,000 x (0.001 to 0.005) - 1 to 5

Number of True Positives -
10 minus 0 - 10

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1 See text for assumptions

antibody-positive persons will be missed if the prevalence were 10 percent, compared to 2 of 100 antibody-positive persons being missed if the prevalence were 0.1 percent. Turning to the false positives, the absolute number of false positives will remain essentially the same with varying prevalences of antibody-positivity, but false positives as a percent of total positives will increase as prevalence decreases. For example, if prevalence were 10 percent, only 1/9,802 to 5/9,806 positive results would be false positives, whereas if prevalence were 0.1 percent, 1/99 to 5/103 positive results would be false positives, and if prevalence were 0.01 percent, 1/11 to 5/15 positive results would be false.

These are best-case estimates. In actual practice, laboratories can be expected to perform at lower levels of accuracy, missing more positive specimens and incorrectly identifying as positive more negative specimens.

Footnotes

1 Meyer, K.B. and Pauker, S.G., "Screening for HIV: Can We Afford The False Positive Rate?" New England Journal of Medicine 317:238-241 (1987).

2 The sensitivity of the tests--i.e., false negatives, or the percent of antibody-containing specimens that would not be detected by the test--is not at issue in this discussion of false positives. Moreover, while the ELISA tests are accepted as having a sensitivity of 100 percent, these tests cannot identify all persons infected with the AIDS virus, nor those persons in the early stages of antibody production. For example, HIV-infected persons may go as long as 6 to 14 months before they develop detectable levels of antibodies to HIV (Ranki, A., Krohn, M., Allain J.P., et al., "Long Latency Precedes Overt Seroconversion in Sexually Transmitted Human-Immunodeficiency-Virus Infection," Lancet ii:589-593 (1987)). Increased sensitivity results in decreased specificity. This relationship is reflected in the following two examples. First, the World Health Organization (WHO) developed a clinical case-definition of AIDS, in which three major and six minor symptoms are used. AIDS is diagnosed if at least two major and one minor symptoms are present. Based on correlations with the presence of antibodies to the AIDS virus or with antigens of the AIDS virus itself, the sensitivity of this clinical case-definition is 54%, and its specificity, 92%. By adding a fourth major symptom to the original three and continuing to use the requirement that at least two major and one minor symptom need to be present in order to make the diagnosis of AIDS, the sensitivity increased from 54% to 75%, but the specificity decreased from 92% to 87% (Bygbjerg, I.C., Schiodt, M., Bakilana, P.B., et al., "Usefulness of a Clinical Case-Definition of AIDS in East Africa," Lancet ii:569 (1987)). Second, the strength of a positive ELISA test is directly related to whether a subsequent Western Blot test will be positive. For example, in one study, highly reactive specimens in the ELISA test were strongly associated with a positive Western Blot, while moderate to weakly reactive ELISA tests were weakly associated with a positive Western Blot (Ward, J.W., Grindon, A.J., Feorino, P.M., et al., "Laboratory and Epidemiologic Evaluation of an Enzyme Immunoassay for Antibodies to HTLV-III," Journal of the American Medical Association 256:357-361 (1986)).

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4 Fust, G., Ujhelyi, E., Hejjas, M., and Hollan, S.R., "Traps of HIV Serology: Independent Changes in Sensitivity and Specificity of ELISA Kits," Presented at the 3rd International Conference on AIDS, Washington, D.C., June 1-5, 1987:49.

5 Cockerill, F.R., Edson, R.S., Chase, R.C., Katzmann, J.A., and Taswell, H.F., " 'False-Positive' Antibodies to Human Immunodeficiency Virus (HIV) Detected by an Enzyme-Linked Immunosorbent Assay (ELISA) in Patients at Low Risk for Acquired Immunodeficiency Syndrome (AIDS)," presented at the 3rd International Conference on AIDS, Washington, D.C., June 1-5, 1987:34.

6 Burke, D.S., Brandt, B.L., Redfield, R.R., et al., "Diagnosis of Human

Immunodeficiency Virus Infection by Immunoassay Using a Molecularly Cloned and Expressed Virus Envelope Polypeptide: Comparison to Western Blot on 2,707 Consecutive Serum Samples," Annals of Internal Medicine 106:671-676 (1987).

7 Burke, D.S. and Redfield, R.R., "False-Positive Western Blot Tests for Antibodies to HTLV-III," Journal of the American Medical Association 256:347 (1986).

8 Saag, M.S. and Britz, J., "Asymptomatic Blood Donor with a False Positive HTLV-III Western Blot," New England Journal of Medicine 314:118 (1986); Roy, S., Portnoy, J., and Wainberg, M.A., "Need for Caution in Interpretation of Western Blot Tests for HIV," Journal of the American Medical Association 257:1047 (1987).

9 Chyang Fang, coordinator of quality control laboratory, American Red Cross, National Headquarters, personal communication with the Office of Technology Assessment, September 25, 1987.

10 Sandstrom, E.G., Schooley, R.T., Ho, D.D., et al., "Detection of Human Anti-HTLV-III Antibodies by Indirect Immunofluorescence Using Fixed Cells," Transfusion 25:308-312 (1985); Stoneburner, R.L., Chiasson, M.A., Solomon, K., and Rosenthal, S., "Risk Factors in Military Recruits Positive for HIV Antibody," New England Journal of Medicine 315:1355 (1986).

11 Centers for Disease Control, "Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS," Morbidity and Mortality Weekly Reports 36(#31):509-515 (1987).

12 Office of Medical Applications of Research, National Institutes of Health, Bethesda, Maryland, "The Impact of Routine HTLV-III Antibody Testing of Blood and Plasma Donors on Public Health," Journal of the American Medical Association 256:1778-1783 (1986).

13 Burke, D.S., Brundage, J.F., Herbold, J.R., et al., "Human Immunodeficiency Virus Infections Among Civilian Applicants for United States Military Service, October 1985 to March 1986," New England Journal of Medicine 317:131-136 (1987).

14 Chyang Fang, coordinator of quality control laboratory, American Red Cross, National Headquarters, personal communication with the Office of Technology Assessment, September 22 and 25, 1987.

15 Fleming, D.W., Cochi, S.L., Steece, R.S., and Hull, H.F., "Acquired Immunodeficiency Syndrome in Low-Incidence Areas," Journal of the American Medical Association 258:785-787 (1987).

16 Texas House Bill No. 1829, section 9.02, signed into law in 1987, contained the following provision:

> When the prevalence rate of confirmed positive HIV infection is .83 percent, as reported under the Communicable Disease Prevention and Control Act (Article 4419b-1, Vernon's Texas Civil Statutes), the Texas Board of Health shall promulgate emergency rules for mandatory testing for HIV infection as a condition for obtaining a marriage license.

Mr. WAXMAN. Our next witness is Dr. Charles McKinney, Director of Education, Gay Men's Health Crisis, who will be accompanied by Mr. Tim Sweeney, Deputy Director of Government Relations.

We are pleased to welcome you to the subcommittee hearing this afternoon. Your prepared statement will be made part of the record in full. We would like to ask you, though, to summarize in no more than 5 minutes.

Dr. McKinney.

STATEMENT OF CHARLES McKINNEY, DIRECTOR OF EDUCATION, GAY MENS' HEALTH CRISIS, ACCOMPANIED BY TIM SWEENEY, DEPUTY DIRECTOR FOR GOVERNMENT RELATIONS

Mr. McKINNEY. Mr. Chairman, members of Congress, my name is Charles McKinney. I am Director of Education for the Gay Mens' Health Crisis in New York.

I come to you from inside the epidemic. We have been dealing for the past 6 years with the crisis on a very first-hand basis. I thank you, on behalf of Gay Mens' Health Crisis and 300 community-based organizations throughout the country who have been fighting the fight against AIDS, for having us here today.

I would like to take the tack of offering you our assistance, assistance that we feel is of particular value because of our experience in dealing with the crisis. In Gay Mens' Health Crisis alone we have dealt with 5,282 clients, people with AIDS and ARC. This number from this single Agency is greater than the combined total number of cases diagnosed in all of Western Europe and the United Kingdom.

We have had this experience from inside and offer you the value of that experience.

We have developed over that period of time a level of expertise, an expertise that is sought out by the Western European countries. We have had visitations from the public health officers and public health officials from all of the Western Europe and European countries, the United Kingdom, Japan, Australia, Canada, Mexico, Brazil. We have been asked to be the guests of governments of Norway, Canada and Australia and have presented our educational programs there.

Our literature is reproduced around the world. The World Health Organization has sought our counsel in developing guidelines in protocols for working with AIDS.

While this is a tribute to the quality of the work we do, it raises a question as to what the role of government has been. We have developed a service delivery model that can provide an immediate response to the needs of individuals with AIDS and the needs of the community with regard to education about AIDS. We have developed an education model that is immediately available to the people where the people are and when they are there.

We do not maintain a program that is a program of service available from 9 in the morning until 5 in the evening and require that people come to us for the information. Rather we go to where the people are when they are there. If that is 4:30 in the morning, if it is 12 midnight, if it is on Saturday, Sunday and holidays, and it is all of those, we go to where the people are to take the educational programs to them.

We can provide and have provided educational service at the lowest cost available. When you channel your funds through the bureaucracy of the Federal Government down to the State and the city bureaucracies, there is not very much left that has not been eaten by administrative costs when it is used to provide services.

We have developed a model in which only a few pennies of any funded dollars is used for administrative costs, and the rest of that dollar goes for direct service. The way we have been able to do this is by enlisting committed volunteerism, volunteerism as it has never really existed before in this country. These are not volunteers who push wheel chairs and deliver flowers to patients' rooms. These are volunteers who make presentations, who teach classes, who facilitate programs, who work directly with clients and do hands-on work.

We are an agency of volunteers. The only way we are able to do the amount of work that we do is through volunteers. We use 76 paid staff members actually to facilitate the work of our 1,700 volunteers who do the work.

We have developed and utilized information systems that have not been accessed by other agencies. Our materials are distributed through the public libraries, in correctional facilities, through the general post office locations throughout the City of New York.

Our programs are documented to be empirically effective. Our literature, as I said, has been reproduced around the world. What we offer, in short, Mr. Chairman, is the use of these 300 agencies in promoting the education that must take place in our fight against AIDS. We urge you to consider NAN, which is the umbrella organization located here in Washington that represents the 300 community-based agencies that are available to you. We would like to help.

Thank you.

[The prepared statement of Mr. McKinney follows:]

Statement of Charles McKinney

Mr. Chairman, Members of Congress:

I am Dr. Charles McKinney, Director of Education, for Gay Men's Health Crisis in New York. I want to thank you on behalf of Gay Men's Health Crisis and over 300 community based organizations that are leading the fight against AIDS in this country, for the opportunity of testifying before you. My purpose today is to offer to the Congress our assistance in the fight against this dread disease.

We offer you the benefit of our experience. Gay Men's Health Crisis was the first, and is the oldest AIDS-service agency in the world. In the 6 years of our existence, we have provided direct care to 5,282 people with AIDS and people with ARC. In fact, this one agency has provided services to a greater number of people with AIDS than the combined cumulative total of diagnosed cases in all of Western Europe and Great Britain. In addition, we provide educational services on an on-going basis, to a greater New York community of over 14,000,000 people.

We offer you the benefit of our expertise. By arrangement of their embassies in New York, public health officers from all of the Western European countries, the United Kingdom, Canada, Mexico, Brazil, Japan and Australia have visited the Gay Men's Health Crisis in the past 18 months. Their purpose has been to draw from our experience and expertise in the development of national policies by their respective governments, for preventing the public health emergency that has occurred, by acquiescence, in the United States.

Health educators from Gay Men's Health Crisis have travelled to Norway, Canada, and Australia, at the request and expense of those governments, to present risk-reduction programs, on site, to leaders of State, and public health officers. The World Health Organization tapped our experience and knowledge when it convened a panel of experts in Geneva, Switzerland, last Spring, to develop guidelines on pre- and post-test HIV counseling.

These citations are a tribute to the quality of the work we do. But they raise questions regarding the locus of leadership in the fight against HIV transmission in the United States.

We offer you the benefit of a service delivery model that is of proven effectiveness in providing education and services to the clients we serve. It is a model that has wide application as part of a National program of AIDS education.

The Gay Men's Health Crisis model is one that is capable of immediate response to the needs of clients as these needs are identified. It is a model that makes services available at the time, and at the place they are needed. It is not a model that provides services between the hours of 9 and 5, Monday through Friday; rather, it is a model that takes services to the people where they are, when those services are needed. If educational intervention is most effective at 4:30 a.m., 12 midnight, holidays, weekends, in bars, or in bathhouses, our services are provided at the times and places the populations we need to reach congregate.

Ours is a service delivery model that uses the money available to it for the delivery of services. A dollar filtered through the Federal bureaucracy to the State, and ultimately to the city, provides only a few pennies for services. In our model, only a few pennies are used for administrative costs, and the major portion of the dollar is used to provide services. This is achieved through a concept of volunteerism that is exclusive with community based organizations. Gay Men's Health Crisis is a volunteer agency, in which 1,700 volunteers provide direct services to clients, under the supervision of a small professional staff of paid employees.

Within this model, GMHC has developed a system for disseminating educational information by utilizing pre-existing networks that reach into every neighborhood and ethnic community in our city. These include the public libraries, General Post Offices, athletic clubs, gymnasiums and health clubs as well as correctional facilities. In addition, we provide peer counseling at Community Information Tables that are stationed in the streets in high traffic areas of New York City. Our Community Support Network utilizes delis, beauty parlors, barber shops and boutiques for the distribution of literature and dissemination of AIDS information.

The risk-reduction programs we have developed demonstrate empirically that sexual behavior can be modified from high risk to low risk. These programs have been replicated world wide. The Ohio State Department of Health will begin using our risk-reduction interventions this Fall in Cincinnati, Cleveland and Columbus.

GMHC literature, which is published in a variety of languages and literacy levels is reproduced throughout the world. The September issue of the *School Library Journal,* which goes to every school library in the country, features GMHC publications as a source of "solid" AIDS information for use in school libraries. The U.S. Public Health Service has purchased copies of *Medical Answers About AIDS* for distribution to all health officers of that service.

I have with me a selection of these publications which I request be made a part of the Congressional Record.

While these citations are a tribute to the quality of our work, they raise questions again regarding the locus of leadership in the fight against AIDS in the United States.

The Federal Government, by its inability and unwillingness to respond to a national health crisis, has lost its credibility. It has lost the confidence of the people. The gap between what government says, and what it does, is blatantly illustrated in the political pandering apparent in the selection of appointees to the Presidential advisory commission in AIDS.

In the absence of a Federal initiative in the fight to contain the AIDS epidemic, the leadership role has been placed on grass roots organizations such as the Gay Men's Health Crisis, and other community based organizations of the National AIDS Network that are located throughout the United States. These organizations, over 300 in number, are eager to assist the Federal Government in meeting its responsibility; but, they cannot be a surrogate for governmental leadership in a national health emergency.

In short, the National AIDS Network of grass roots, community based organizations, offers you the benefit of its experience and expertise, its service delivery systems, and a model that is both cost effective and efficient. It is a model that has credibility with its constituency, and the confidence of its constituency.

A mobilized grass roots effort, in combination with the resources and leadership of the Federal Government, provide the strategic elements for success in a national campaign to contain and control the HIVirus. We ask the Congress of the United States to act on behalf of its people. That is the conclusion of my testimony Mr. Chairman. Thank you.

Mr. WAXMAN. Thank you very much, Dr. McKinney. We appreciate your testimony.

The bells have rung indicating that we have a vote on the House floor. Before we begin any questions, I would like to recess for us to respond to that vote and then return as soon as possible to pursue questions and answers.

[Brief recess.]

Mr. WAXMAN. Thank you.

The meeting of the subcommittee will come back to order. Dr. McKinney, let me ask you this: do you think that the same kind of educational efforts that you have been involved with should be used for the general public?

Or do you think we ought to have tailored educational efforts to reach different groups?

Mr. MCKINNEY. Mr. Waxman, the general public is made up of many publics, and the materials that we have developed have been specifically tailored to each of those populations. I think it would be an error to think that the educational effort of Gay Men's Health Crisis has been targeted exclusively to the Gay and bisexual community.

It has not. The major effort has been to the general public, to inform the general public. Our three missions, our three target audiences, are the general public; health care providers and mental health workers; and, third, and specifically for Gay and bisexual men, risk reduction education.

I would say yes, that many of the methods that we have developed are quite applicable to the general public in the development of any educational program. However, the specific audience must be considered in tailoring the program, so that what we have learned will be useful.

Whether or not this is the most useful approach via television is a question that would have to be deliberated. Whether it is for a classroom setting, yes: we found that to be so.

Mr. WAXMAN. Mr. Dannemeyer.

Mr. DANNEMEYER. Is the Gay Mens' Health Crisis in New York the one that received a grant this fiscal year for some $670,000 from the Federal Government?

Mr. MCKINNEY. No, sir.

Mr. DANNEMEYER. Have you received a grant at all, in any amount?

Mr. MCKINNEY. Yes, sir.

Mr. DANNEMEYER. How much was the amount?

Mr. MCKINNEY. We are in the second year of a research program that is funded by the Centers for Disease Control, and for a 15-month period. The continuation grant was $434,000.

Mr. DANNEMEYER. I see. I have some material here. Do we have staff person that can hand this to the witness, please?

Mr. MCKINNEY. Yes, sir. I recognize this material.

Mr. DANNEMEYER. Is this material published by the Gay Men's Health Crisis?

Mr. MCKINNEY. Yes, sir.

Mr. Dannemeyer. When was it published?

Mr. McKinney. There are a couple of different—it has been over the 1986–1987 fiscal year, and 1987–1988; each of these has come out, it has been timed about 2 to 3 months apart. It was not all published at one time.

Mr. Dannemeyer. Was it published and disseminated by the Gay Men's Health Crisis at a time when you were receiving this Federal money?

Mr. McKinney. Yes.

Mr. Dannemeyer. How do you go about getting a copy of these documents that I have handed to you?

Mr. McKinney. You may call or write to Information Services of the Gay Men's Health Crisis. On the basis of a telephone call, for instance, you would be informed that there are three packets of material that are already made up.

I have brought a selection of those materials, which I would like to ask be entered into the record today. One is an Info Pack, which is an information pack, which is targeted to the general public.

A second is a Gay Pack, which is targeted to the Gay and bisexual community. It contains everything that would be targeted to the general public, plus the safer sex comics, and a couple of other pieces that are targeted exclusively to the Gay and bisexual community.

Mr. Dannemeyer. Did you mean to infer, sir, that the documents that I handed you fit within the category of the safer sex comics? Is that what you said?

Mr. McKinney. Yes. That's what these——

Mr. Dannemeyer. That's what you would call that?

Mr. McKinney. That's what is captioned on what you gave me, yes.

Mr. Dannemeyer. There is no doubt in the mind of this member that the material that I handed you is pornographic.

Mr. McKinney. Yes, sir.

Mr. Dannemeyer. The fact that you would distribute it—we live in a free country, we have a free press. If you can find somebody that has an interest in that literature, although—you distribute this literature by mail?

Mr. McKinney. Yes. When requested specifically, we do.

Mr. Dannemeyer. I would submit, sir, that if you distribute that pornographic material by mail, you are violating a Federal law which prohibits the use of the U.S. Mails to mail pornographic material.

I just don't think that Federal taxpayers' dollars should be directly, or indirectly, assisting an organization such as yours in disseminating pornographic material of this type.

Mr. Sweeney. Congressman, if I may? We do not use——

Mr. Dannemeyer. You can answer this: why do you distribute this type of material? What's the purpose?

Mr. McKinney. I think that the answer was given to you yesterday. We publish material at all literacy levels and in different languages that are targeted for different groups, and that are effective and useful for different groups

The safer sex comics have been designed for specific groups. They are the most effective way of communicating with those groups.

You have used the term pornographic material; we call that educational literature.

Mr. SWEENEY. Congressman Dannemeyer, we want to make it very clear. No Federal funds are used in the printing of these materials whatsoever. You will see in the record of the materials that we submitted, an order form where you have to order this material, should you want to get it.

It is right here.

Mr. DANNEMEYER. I think, in your analysis, that is probably a correct statement. But from this Member of Congress' viewpoint, I don't believe that the people of this country are comfortable with Federal taxpayers' dollars going to an organization that distributes this kind of material, with all due respect to the purpose you have in mind.

Mr. SWEENEY. We believe it is our right and our responsibility to educate, and to reach people with lifesaving information. We believe that the safer sex comics, in fact, do reach a certain person. They will hear a message and, hopefully, act responsibly, and protect themselves and their sexual partners.

Mr. DANNEMEYER. I guess we have a different point of view on that. Thank you, Mr. Chairman.

Mr. WAXMAN. It is your position that Federal dollars are not being used, directly or indirectly, for these publications?

Mr. SWEENEY. That is correct. The safer sex comics are not used in the research program, which is Federally funded.

Mr. WAXMAN. You wanted to submit some information to us. We will pleased to receive that.

Mr. DANNEMEYER. Mr. Chairman, may I ask that this material that I showed to the witness be placed in the record?

Mr. WAXMAN. We will be pleased to review that material.

[The material referred to may be found in subcommittee files.]

Mr. WAXMAN. I have asked that a transcript of the National AIDS Hotline tape message be included for the record. Without object?

I would also ask that their materials that are sent to callers of that Hotline, if requested, be part of the record.

[Testimony resumes on p. 262.]

[The following materials were submitted for the record:]

ASHA: National AIDS Hotline

Taped Message

4 Actors: 1 Male - "Announcer"
1 Male - "Character Male"
1 Female - "Female Lead"
1 Female - "Black Female"

Announcer (A)

This is the Public Health Service National AIDS Hotline...operated by the American Social Health Association.

In this 4 minute message, we'll give you basic information on the A quired I mmuno D eficiency S yndrome - AIDS.

Female Lead

We'll tell what AIDS is and how to protect yourself against infection...

Character Male

We'll talk about the blood test that detects the AIDS infection and where testing is available...

Black Female

And we'll have a word for women planning on having a baby who are concerned about AIDS.

Female Lead

Then, if you have any questions or want to be sent written information, we'll give you the phone number to get answers from our live operators.

Announcer

AIDS is caused by a virus. It's known as the Human Immunodeficiency Virus: H-I-V. Most people infected with the AIDS virus don't feel sick or show any signs of illness...

There are people who do get very sick. The AIDS virus damages part of their body's immune system and they get serious diseases which are rarely a threat to human beings. So far, in America, most of these people have been gay and bisexual men, intravenous drug users, people with the disease hemophillia... and sexual partners of all these groups. Also, some people did get the AIDS virus through blood transfusions. And, more and more cases of AIDS are now being seen in heterosexuals.

Black Female

What's the link between all these groups? (1) sexual contact and (2) exposure to blood. Because, that's how the AIDS virus is transmitted or spread.

You can get the AIDS virus by having unprotected sexual intercourse with an infected person... or by exposure to their blood...mostly, that happens when intravenous drug users share needles or syringes... and finally...an infected mother can give her child the virus during pregnancy or at birth. Women who might be infected should talk to their doctor or family planning service before getting pregnant. Here's why:

Character Male

There is now a blood test that detects signs of the AIDS virus...it identifies "antibodies" to the AIDS virus - that's what your body produces to try and defend itself against the infection.

This blood test is insuring that America's blood supply is safe. Every unit of donated blood is now tested and, if positive, it's not used.

Female Lead

If you think you've been exposed to the AIDS virus and are interested in having your blood tested, you should see your personal physician - or go to one of the new special testing centers, where there is counseling available and test results are confidential. We'll give you the number for more test information.

Announcer

...That's the basic story...The AIDS virus is not spread like the cold or influenza or the measles...it's spread mainly by sexual intercourse and by exposure to blood...

If you don't want to get infected, there are only a few things to remember:

Black Female

One of the surest ways to avoid infection is not to have sexual intercourse or other sexual relations: That's called abstinence. And there's this important advise from the U.S. Surgeon General...Listen...

Koop

The best protection against the infection, right now, barring abstinence, is the use of a condom. A condom should be used during sexual relations from start to finish with anyone whom you are not absolutely sure is free of the AIDS virus.

Announcer

Remember even a condom is not a guarantee of safety; Today everyone needs to be "prudent" about sexual relations, because of AIDS and other sexually transmitted diseases.

Character Male

And finally do not abuse intravenous drugs; if you can't stop, please don't ever share, or lend, or even reuse needles or syringes.

Lead Female

Now, if you want more information by phone or by mail - take down this number 1-800-342-7514. There's a person ready to provide answers 24 hours a day. The number again is 1-800-342-7514. Thank you.

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Update: Human Immunodeficiency Virus Infections in Health-Care Workers Exposed to Blood of Infected Patients

Six persons who provided health care to patients with human immunodeficiency virus (HIV) infection and who denied other risk factors have previously been reported to have HIV infection. Four of these cases followed needle-stick exposures to blood from patients infected with HIV (*1-4*). The two additional cases involved persons who provided nursing care to persons with HIV infection. Although neither of these two persons sustained needle-stick injuries, both had extensive contact with blood or body fluids of the infected patient, and neither observed routinely recommended barrier precautions (*5,6*).

CDC has received reports of HIV infection in three additional health-care workers following non-needle-stick exposures to blood from infected patients. The exposures occurred during 1986 in three different geographic areas. Although these three cases represent rare events, they reemphasize the need for health-care workers to adhere rigorously to existing infection control recommendations for minimizing the risk of exposure to blood and body fluids of all patients (*7-9*).

Health-Care Worker 1: A female health-care worker assisting with an unsuccessful attempt to insert an arterial catheter in a patient suffering a cardiac arrest in an emergency room applied pressure to the insertion site to stop the bleeding. During the procedure, she may have had a small amount of blood on her index finger for about 20 minutes before washing her hands. Afterwards, she may also have assisted in cleaning the room but did not recall any other exposures to the patient's blood or body fluids. She had no open wounds, but her hands were chapped. Although she often wore gloves when anticipating exposure to blood, she was not wearing gloves during this incident

The patient with the cardiac arrest died A postmortem examination identified *Pneumocystis carinii* pneumonia, and a blood sample was positive for HIV antibody by enzyme immunoassay (EIA) and Western blot methods. Twenty days after the incident, the health-care worker became ill with fever, myalgia, extreme fatigue, sore throat, nausea, vomiting, diarrhea, a 14-pound weight loss, and generalized lymphadenopathy which her physician diagnosed as a viral syndrome. That illness lasted 3 weeks She felt much better 9 weeks after the incident, and, when she was examined 6 months after the incident, all signs and symptoms had resolved She had donated blood 8 months before the incident and was negative for HIV antibody by EIA. She donated again 16 weeks after the incident and was positive for HIV by EIA and Western blot (bands p24 and gp41). Serum samples obtained 20 and 23 weeks after the incident were also positive for HIV antibody She stated that for over 8 years her only sexual partner had been her husband, who denied risk factors for HIV and was seronegative for HIV antibody. She denied ever receiving a blood transfusion, ever using intravenous drugs, or having any needle sticks or other significant exposures to blood or body fluids in the past 8 years. Her serologic test for syphilis was negative. Fifteen other employees who assisted in the care of the patient were seronegative at least 4 months after the exposure.

Health-Care Worker 2: A female phlebotomist was filling a 10 ml vacuum blood collection tube with blood from an outpatient with a suspected HIV infection when the top of the tube flew off and blood splattered around the room, on her face, and in her mouth. She was wearing gloves to protect her hands and was wearing eyeglasses so she did not think she got any blood in her eyes. She had facial acne but no open wounds. She washed the blood off immediately after the exposure. The outpatient's blood sample was positive for HIV antibody by EIA and Western blot, and a hepatitis B surface antigen test was negative. The phlebotomist's EIA was negative the day after the incident and again 8 weeks later. When she donated blood 9 months after the exposure, she was positive for HIV antibody by EIA and Western blot (bands p24 and gp41). She has had no symptoms. She denied having any sexual contact during the previous 2 years, ever using drugs intravenously, or ever receiving a transfusion

Two months after the incident, she scratched the back of her hand with a needle used to draw blood from an intravenous drug abuser of unknown HIV-antibody status. She did not bleed as a result of the scratch and has not had any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative. A coworker who was splattered with blood on the face and in the mouth during the same incident remains seronegative 1 year after the incident.

Health-Care Worker 3: A female medical technologist was manipulating an apheresis machine (a device to separate blood components) to correct a problem that developed during an outpatient procedure when blood spilled, covering most of her hands and forearms. She was not wearing gloves. She does not recall having any open wounds on her hands or any mucous-membrane exposure. However, she had dermatitis on one ear and may have touched it. She washed the blood off herself and the machine several minutes after the spill. The patient undergoing the apheresis had denied risk factors for HIV infection. However, a blood sample from the patient was positive for HIV antibody by EIA and Western blot methods and negative for hepatitis B surface antigen the next day. The technologist's HIV-antibody tests were negative 5 days after the exposure and again 6 weeks later. Eight weeks after the exposure, she had an influenza-like illness with fever, myalgia, diarrhea, hives, and a pruritic red macular rash on her arms and legs. The illness resolved after a few weeks, and her physician thought the illness was probably a viral syndrome. Three months after the incident, she was positive for HIV antibody by EIA and Western blot methods (band p24 alone). Four months after the incident, a Western blot was positive (bands p24 and gp41). She indicated that for more than 8 years her only sexual partner had been her husband, who denied risk factors for HIV infection and was seronegative for HIV antibody. She denied ever receiving a transfusion, ever using intravenous drugs, or having any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative. She has an immunologic disorder which had been treated with corticosteroids in the past, but she had not taken any immunosuppressive medication for the past year. A coworker with a similar exposure during the same procedure remains seronegative after 3 months.

Reported by: Hospital Infections Program and AIDS Program, Center for Infectious Diseases, CDC.

Editorial Note: Three instances of health-care workers with HIV infections associated with skin or mucous-membrane exposure to blood from HIV-infected patients are reported above. Careful investigation of these three cases did not identify other risk factors for HIV infection, although unrecognized or forgotten needle-stick exposures to other infected patients cannot be totally excluded. The exact route of transmission in these three cases is not known. Health-Care Worker 1 had chapped hands, and the duration of contact with the blood of the patient experiencing a cardiac arrest may have been as long as 20 minutes. Health-Care Worker 2 sustained contamination of oral mucous membranes. This individual also had acne but did not recall having open lesions. In addition, she had sustained a scratch from a needle used to draw blood from an intravenous drug abuser of unknown HIV-infection status. Health-Care Worker 3 had a history of dermatitis involving an ear. Health-Care Workers 1 and 3 were not wearing gloves when direct contact with blood occurred. Health-Care Worker 2 was wearing gloves, but blood contaminated her face and mouth.

Three ongoing prospective studies provide data on the magnitude of the risk of HIV infection incurred when health-care workers are exposed to blood of infected patients through needle-stick wounds or contamination of an open wound or mucous membrane. In a CDC cooperative surveillance project (*10*), a total of 1,097 health-care workers with parenteral or mucous-membrane exposure to the blood of patients with AIDS or other manifestations of HIV infection had been enrolled as of March 31, 1987. Needle-stick injuries and cuts with sharp objects accounted for 969 (89%) of the exposures to blood; 298 of these had paired serum samples tested for HIV antibody. One (0.3%) seroconverted (*2*), indicating that the risk of transmission during these exposures is very low. In addition, 70 health-care workers had open wounds exposed to blood, and 58 had mucous membrane exposed to blood. Postexposure serum samples from 82 of these 128 workers have been tested for antibody to HIV; none was seropositive.

In a study at the National Institutes of Health (*11*) through April 30, 1987, none of the 103 workers with percutaneous exposures and none of the 229 workers with mucous-membrane exposures to blood or body fluids of patients with AIDS was seropositive. At the University of California (*12*), none of 63 workers with open wounds or mucous membranes exposed to blood or body fluids of patients with AIDS was seropositive. Although the precise risk of transmission during exposures of open wounds or mucous membranes to contaminated blood cannot be defined, these studies indicate that it must be very low.

The three cases reported here suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV. The magnitude of the risk is not known since data on the frequency with which such exposures occur are not available. Skin and mucous-membrane exposures are thought to occur much more commonly than needle sticks, and the risk associated with skin or mucous-membrane exposures is likely to be far lower than that associated with needle-stick injuries. Nonetheless, the increasing prevalence of HIV infection increases the potential for such exposures, especially when routinely recommended precautions are not followed

It is unlikely that routine serologic testing for HIV infection of all patients admitted to hospitals would have prevented these exposures since two of the three exposures occurred in the outpatient clinic setting, and one occurred during a resuscitation effort in an emergency room shortly after the arrival of the patient. At the time of exposure, Health-Care Worker 2 suspected that the source patient was infected with HIV, but Health-Care Workers 1 and 3 did not. The hospital where Health-Care Worker 3 was exposed has a protocol for apheresis which normally involves HIV-antibody testing of donors; however, such testing was not done in advance of the procedure. Previous CDC recommendations have emphasized the value of HIV serologic testing for patient diagnosis and management and for prevention and control of HIV transmission (*13*) and have stated that some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients (*7*). Such testing may also provide an opportunity to reduce the risk of HIV infection to health-care workers, but it has not been established that knowledge of a patient's serologic status increases the compliance of health-care workers with recommended precautions

These cases emphasize again the need to implement and strictly enforce previously published recommendations for minimizing the risk of exposure to blood and body fluids of all patients in order to prevent transmission of HIV infection in the workplace and during invasive procedures (*7-9*).

1. As previously recommended, routine precautions must be followed when there is a possibility of exposure to blood or other body fluids. The anticipated exposure may require gloves alone (e.g., when placing an intravascular catheter or handling items soiled with blood or equipment contaminated with blood or other body fluids). Procedures involving more extensive contact with blood or potentially infective body fluids (e.g., some dental or endoscopic procedures or postmortem examinations) may require gloves, gowns, masks, and eye-coverings. Hands and other contaminated skin surfaces should be washed thoroughly and immediately if accidentally contaminated with blood (*7*). These precautions deserve particular emphasis in emergency care settings in which the risk of blood exposure is increased and the infectious status of the patient is usually unknown (*14*).

2. Previous recommendations have emphasized management of parenteral and mucous-membrane exposures of health-care workers*. In addition, health-care workers who are involved in incidents that result in cutaneous exposures involving large amounts of blood or prolonged contact with blood—especially when the exposed skin is chapped, abraded, or afflicted with dermatitis—should follow these same recommendations. Moreover, serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

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*If a HCW [health-care worker] has a parenteral (e.g., needlestick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III/LAV [sic] infection If the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III/LAV [sic] infection. If the source patient has AIDS or other evidence of HTLV-III/LAV [sic] infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV [sic] infection as soon as possible after the exposure, and, if seronegative, retested after 6 weeks and on a periodic basis thereafter (e g , 3, 6, and 12 months following exposure) to determine if transmission has occurred During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCWs should receive counseling about the risk of infection and follow U.S. Public Health Service (PHS) recommendations for preventing transmission of AIDS (*15,16*). If the source patient is seronegative and has no other evidence of HTLV-III/LAV [sic] infection, no further follow-up of the HCW is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the source patient was infected (7)

The Prevention of Acquired Immunodeficiency Syndrome in the United States

An Objective Strategy for Medicine, Public Health, Business, and the Community

Donald P. Francis, MD, DSc, James Chin, MD, MPH

Human immunodeficiency virus (HIV) is one of the most virulent infectious agents ever encountered. This virus, estimated to kill up to a half of those infected, has spread to more than 1 million Americans. There is no safe and effective treatment. Nor is there a vaccine. From our understanding of HIV transmission, further spread of the virus can be stopped by the use of various techniques. The combined use of education-motivation-skill building, serologic screening, and contact tracing/notification could eliminate or substantially reduce transmission. To accomplish this reduction an immense concerted effort by physicians, public health practitioners, business, and community organizations is required to get across the simple prevention messages. Those messages are: (1) Any sexual intercourse (outside of mutually monogamous or HIV antibody-negative relationships) must be protected with a condom. (2) Do not share unsterile needles or syringes. (3) All women who may have been exposed should seek HIV-antibody testing before becoming pregnant and, if positive, avoid pregnancy. Only through a concerted, vigorous, and sustained prevention program that deals frankly with this problem will those individuals at risk be reached and motivated to take personal responsibility to protect themselves. Without such an effort, acquired immunodeficiency syndrome will continue to kill ever-increasing numbers of Americans.

(*JAMA* 1987;257:1357-1366)

AS OF early 1987, about 30 000 cases of acquired immunodeficiency syndrome (AIDS) were reported in the United States, and it is expected that another 250 000 or more will be recorded by 1991.[1] In some communities, such as San Francisco, where the toll of over 1000 deaths recorded as of early 1986 had already exceeded the number of deaths of soldiers and sailors from this city for World War I, World War II, the Korean War, and the Vietnam conflict combined, the pain and suffering of patients, their families, and their friends has been immense. In addition, the social damage—in terms of valuable and productive persons lost and medical expenditures incurred—has been enormous[2] and is still increasing.

Current evidence suggests that the etiologic agent of AIDS has been present in localized areas of central Africa for at least several decades,[3] and only during the past few years has it been spreading extensively in Africa, the United States, Haiti, and Western Europe.[1] The large numbers of cases of AIDS now being documented in the United States, and throughout the world, are primarily a result of infections that occurred in the 1970s and early 1980s, before the causative virus was isolated and its pathogenesis and transmission understood. As such, the current disaster was, to a large extent, an unpreventable one that now requires an immediate and effective medical and social response to minimize the pain, suffering, and social upheavals caused by these silent infections of years past.

See also pp 1367 and 1376.

With our current understanding of AIDS, it is clear that virtually all future infections can, at least theoretically, be prevented. Given the opportunity (ie, information, motivation, and skills), individuals should be able to modify their behaviors to protect themselves from infection. The major question is, can our society unite to impart effectively the needed information, motivation, and skills to those at risk to stop this epidemic? The answer to this question depends on, first, having a commitment to intervene effectively; second, developing a reasonable, scientifically and socially sound intervention plan; and third, implementing that plan as rapidly as possible.

This report will review the current knowledge regarding the pathogenesis and transmission of the AIDS virus in the United States, outline a prevention plan based on that knowledge, and describe the major problems confronting effective prevention and control.

THE VIRUS AND ITS PATHOGENESIS

Human immunodeficiency virus (HIV)[4] (also known as lymphadenopathy-associated virus,[5] human T-cell lymphotropic virus type III,[6] and AIDS-associated retrovirus[7]), the etiologic agent for AIDS, is a retrovirus capable of replicating in a limited number of cells in the human body, including lymphocytes,[6,7] macrophages,[8] and cells of the central nervous system.[9,10] Typical of retroviruses, HIV integrates its genome into the genome of the host cell, after which progeny viruses are produced. Soon after infection, antibody to several proteins of HIV develop, but these antibodies are not necessarily protective. Indeed, one of the most remarkable aspects of HIV is its propen-

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sity for producing a persistent viremic ("carrier") state in a high proportion of infected people despite the presence of antibody (see "The Significance of Seropositivity" section). The pathogenesis of HIV is related to the destruction of the "helper" (T4) subset of T lymphocytes, which are critical in maintaining immunologic competence. In addition, neurologic disease appears to be a direct result of HIV-induced destruction of brain cells.[10]

TRANSMISSION

Transmission of any human virus requires a portal of exit, survival through the environment into which it is released, and entrance into a susceptible host with establishment of infection in a cell capable of supporting replication. The HIV has been isolated from fluids obtained from a variety of body sites, including blood,[6,7,13] semen,[12,13] vaginal fluid,[14,15] tears,[16] and saliva.[17] Epidemiologic studies have established that those fluids that provide sufficient virus for transmission seem to be limited to blood,[18-20] semen,[21,22] and vaginal secretions.[23,24] Presumably, the presence of lymphocytes in these fluids increases the concentration of infectious virus and may be important, or even essential, for transmission.

Those sites best suited for the establishment of infection after exposure appear to be the vascular system (including open wounds of the skin[25]), the penis (presumably the urethra), the vagina,[26] and the rectum. The oral mucosa appears relatively inhospitable to the establishment of infection,[21,28] yet the infection of an infant, presumably through breast-feeding,[27] leaves room for concern regarding the placement of potentially infectious fluids on upper gastrointestinal tract mucous membranes (at least of newborn infants).

Sexual Transmission

The HIV is effectively transmitted by sexual contact between men,[21] from men to women,[22,24,29,30] and from women to men.[23,24,30-33] The difference in transmission efficiency, if any, between anal intercourse and vaginal intercourse is not known and continues to be disputed. What is known is that many persons have been infected by both types of intercourse. Between men, it appears that receptive anal intercourse is a more effective means of transmission than is insertive anal intercourse or any type of oral-genital intercourse.[34] With vaginal intercourse it appears that transmission rates from men to women or from women to men may be similar.[35] The exact risk of infection for a susceptible person having a single sexual encounter with an infected partner is unknown. There are individuals, both heterosexual and homosexual, who have had repeated sexual relations with known infected persons without having been infected. Yet there are others who report having had only one sexual encounter and have then developed AIDS. In addition, a report from Australia[36] that four of eight women developed an infection after they were inseminated with semen from an infected sperm donor, and a report of infection of a female chimpanzee by intravaginal inoculation,[37] suggest that a single encounter with HIV is sufficient in some situations to infect.

Blood-Borne Transmission

Inoculation of HIV intravenously appears to be an efficient means of transmission regardless of whether the inoculum contains cell-free virus[20] or cell-associated virus.[8] The major determinant of outcome of exposure appears to be the amount of virus inoculated. Large inocula given in the form of transfused blood almost universally result in infection,[19] whereas small inocula of blood on the end of a needle seldom result in infection.[38] This appears to be a function of the concentration of infectious virus in blood, which is relatively low,[6] and the amount of blood on the end of a needle, which is small. The lack of hospital- or laboratory-acquired HIV infections indicates that unbroken skin is probably a good barrier to transmission; however, reports of presumptive infection through inflamed skin are of potential concern.[25]

Perinatal Transmission

Transmission from infected mothers to their infants can apparently occur in utero,[27] during parturition,[39] or during postpartum breast-feeding.[27] The relative efficiency of perinatal transmission is probably quite high but has not been well established and may vary considerably between women.[38,39]

Other Routes of Transmission and Potential for Change

Despite detailed serologic studies of close contacts of infected persons[38-41] and investigations of AIDS cases,[42] no other form of transmission has been documented. A single episode of possible intrahousehold transmission between two brothers has been reported.[43] The few instances of transmission to hospital workers can be attributed to contact with or inoculation of blood.[44] Two out-of-hospital instances of HIV transmission to individuals who performed duties similar to hospital nurses[25,45] are presumably similar to the rare in-hospital transmission episodes. In total, the relative absence of HIV transmission in hospitals, even to those who have received accidental needle sticks from infected patients, is striking and in direct contrast to the high infection rate seen with hepatitis B virus after such accidents.

Regarding future projections of transmission pattern changes, concern has been raised about the genetic variability of HIV. Could genetic changes of HIV result in increased transmissibility or transmission by other-than-recognized routes? Some have suggested that a dramatic mutation of a preexisting African strain allowed this virus to change its epidemiologic characteristics in Africa and eventually spread throughout the world. But there are no African isolates before 1976 to support or disprove this hypothesis. Moreover, other equally plausible explanations have some support in fact. For example, the apparent increased transmission recently observed in urban Africa is likely due to social rather than viral change. Over the past few decades there have been major population shifts from rural villages to urban centers in many African countries. This urbanization, together with the proliferation of prostitution in cities, and possibly the use of contaminated needles and blood transfusions in hospitals and clinics, could be the root causes of the amplification of transmission in Africa of a virus that may have changed little over the years.

Support for this hypothesis comes from the fact that despite considerable variation of the nucleotide sequences of various HIV isolates, the transmission patterns of the virus have remained remarkably consistent. Indeed, since the arrival of HIV in the United States, the transmission patterns have been marked more by consistency than by change. The proportional distribution of cases among the various risk groups has remained essentially constant despite a marked increase in the number of cases, multiple generations of passage through humans, and wide dispersion through different racial groups.

NATURAL HISTORY OF INFECTION

Infection with HIV carries a poor prognosis. Although follow-up of seropositive individuals in the United States has been limited by the relatively recent introduction of the virus into this country, already it is clear that the mortality from this virus is high. Between 13% and 34% of antibody-positive homosexual men, intravenous (IV) drug users, and hemophiliacs followed up for up to six years[46,47] have developed AIDS. Such dramatic proportions of severe disease development among infected individuals are frightening, making HIV among the most dangerous viruses affecting humans (Table 1). Furthermore, when these mortality figures are joined with the high prevalence (25% to 40%) of other AIDS-related conditions, the possibility of eventual encephalopathic conditions, and the realization that the current observation times for infected persons represent only a fraction of the potential time during which diseases may become apparent in the natural history of this virus, concern regarding the severity of HIV grows even greater.

Many have speculated that there may be cofactors for the development of AIDS. Such cofactors could have a major effect at two quite separate times—one early on, affecting the acquisition of infection, and one later, affecting the progression toward disease once infection has occurred. Some have hypothesized that preexisting conditions, such as immunosuppression or antigen exposure, may increase the likelihood of becoming infected after exposure to HIV. This has not been confirmed in laboratory experiments with chimpanzees, where infection has been readily established with IV or intravaginal exposure to HIV in the absence of immunosuppression or stimulation with other antigens.[8] Yet outside the laboratory, certain conditions, especially those that facilitate transmitted virus coming in contact with susceptible target cells (macrophages or lymphocytes), may improve the chance of successful transmission. Thus, one could hypothesize that conditions that increase the populations of macrophages or lymphocytes at potential sites of virus exit and entry may well be cofactors for infection.

Few cofactors for disease progression have been found. Some have hypothesized that reexposure to HIV may increase one's chances for disease, yet there are no other models in virology, at least that we are familiar with, that would support this. Furthermore, such a hypothesis is difficult to reconcile with the observation of AIDS following exposure to 1 unit of infected blood. Yet, something must determine why some infected persons progress rapidly to develop AIDS, while others either progress slowly to the irreversible immune state or do not develop AIDS. One major factor is time. Those who have been infected the longest have the highest risk of developing AIDS. Indeed, until cohorts of infected individuals are followed up long enough to observe the entire natural history of this infection and the collected information used to control for the time factor, it is extremely difficult to sort out the importance of other possible cofactors.

Despite these limitations, some other factors (eg, age) appear to be important. Evidence indicates that infants may have extremely high rates of progressive disease (M. Rogers, MD, written communication, Centers for Disease Control, Atlanta, June 1986). At the other extreme of the age spectrum, older homosexual men appear to have higher disease progression rates than younger ones. Since pregnancy may also increase the rates of AIDS in infected women, hormonal levels may also influence outcome. Repeated stimulation with foreign antigens, another possible cofactor, has often been hypothesized as a potential enhancer of viral replication since, in the laboratory, lymphocytes stimulated with mitogens replicate the virus more efficiently than do nonstimulated lymphocytes.[3]

Other in-combination influences have been studied in regard to Kaposi's sarcoma, since it is so prevalent in homosexual patients with AIDS as compared with others. Amyl and butyl nitrite ("poppers"), stimulants commonly used by some homosexual men, were originally proposed as possible causes of AIDS. They have subsequently been suggested as cofactors in Kaposi's sarcoma, but this latter issue remains open as other factors (eg, coinfecting viruses) have not been thoroughly investigated.

THE SIGNIFICANCE OF SEROPOSITIVITY

The serologic tests for detecting HIV antibodies have proved to be extremely sensitive and specific. Individuals whose serum tests strongly reactive by enzyme-linked immunosorbent assay (ELISA) or, if borderline reactive by ELISA, are also positive by appropriately done Western blot or immunofluorescence asssay may be considered to have been infected by the virus. But, in some situations, misinformation can be generated by ELISA testing alone. The ELISA test, when used in groups with a high prevalence of infection, like sexually active homosexual men, has a high positive predictive value. However, when it is used in groups with a low prevalence of infection, most of the "positive" results are low-reactive ones and generally turn out to be false-positive. Also, as with other viral infection models, immediately after infection viral replication can occur in the absence of a detectable serologic response. For HIV this "window phase" appears to be a matter of a few weeks in most individuals, but it has been known to last up to six months (J. Groopman, MD, written communication, January 1987). Except during this window phase, current data indicate that a negative ELISA test result means in virtually all instances that the individual has not been infected with HIV.

Since HIV integrates in the host's genes and, thus, can presumably stay latent in an infected host, all antibody-positive persons must be considered potentially infectious. In actuality, only about 65% of antibody-positive persons have had recoverable virus circulating in their blood at any given time, based on one isolation attempt. Whether the antibody-positive but virus-negative persons are truly free of infectious virus or whether they represent only a transient virus-negative state, or whether currently available laboratory techniques are not sensitive enough to detect infectious virus in them, will be clarified only by additional studies.

PREVENTION OF TRANSMISSION

At the present time, there are no effective vaccines or chemoprophylactic drugs for the prevention of HIV infections. Likewise, no effective treatment exists for HIV infection once established. Since there are no known animal or insect vectors and the virus is not transmitted by the respiratory or fecal-oral route, prevention of HIV transmission must be directed at person-to-person spread via sexual, blood-borne, and perinatal routes (Table 2). (J. C. Chermann, MD, in a June 1986 presentation at Colloque des "Cent Gardes." Paris, reported that he detected HIV-related nucleic acid in a variety of insects in Africa, but no evidence of viral infections of insects or transmission by insects exists.)

The following approaches for prevention are presented according to the im-

Table 1.—Mortality From Viral Infections*

Infection	% Deaths
Rabies	99
Ebola/Marburg	25-60
Smallpox	
Major	30
Intermediate	3-11
Minor	1
HIV (AIDS)†	25-50
Hepatitis B (acute and chronic)	5
Lassa	3-5
Polio	<0.1

*Data from Evans.

†HIV indicates human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome. A National Academy of Science/Institute of Medicine committee has projected that 25% to 50% of persons will develop AIDS within five to ten years of acquiring an HIV infection. The also stated that an even higher percentage progressing to frank AIDS after ten years cannot be ruled out with the available data.

Table 2 —The AIDS Prevention Message to the Community*

To Stop Needle-Borne Transmission
- Don't share unsterile needles or syringes

To Stop Sexual Transmission:
- If you are going to have sex,† use the following guidelines to decrease your risk of infection
  - **Absolutely Safe**
    - Mutually monogamous relationship‡
  - **Extremely Safe**
    - Noninsertive§ sexual relations
  - **Very Safe**
    - Insertive sexual relations using a condom‖ (and nonoxynol 9–containing spermicide)
  - **Risky**
    - Anything else

To Stop Perinatal Transmission:
- If you could have been exposed to HIV, get tested for antibodies. If you are positive, don't become pregnant

*AIDS indicates acquired immunodeficiency syndrome; HIV, human immunodeficiency virus.

†Vaginal or rectal intercourse. Decreasing one's sexual partners will decrease the chance of being exposed to an infectious person.

‡Assuming neither partner previously exposed or proven to be noninfected (by antibody test).

§Excludes vaginal or rectal intercourse. Oral-genital risk, see text.

‖Condoms must be properly used at all times with all partners.

portant and documented routes of HIV transmission in the United States. They represent the only available methods of limiting or preventing HIV infections at the present time and in the foreseeable future. These methods should be actively implemented. The exact effectiveness of some of the proposed measures has not been fully documented. Nevertheless, they should be implemented, as soon as possible, together with parallel efficacy evaluation studies.

Sexual Transmission

Sexual transmission of HIV can be avoided if infected persons do not have vaginal or anal intercourse with susceptible persons or if, during intercourse, effective barrier techniques are used.

There is no risk of sexual transmission of HIV for those who practice sexual abstinence. Furthermore, there is no risk of infection if neither partner is infected. This would be the case for couples who have been mutually monogamous since the introduction of HIV in the United States (presumably in the mid-1970s). It would also be true (to the limits of current laboratory technology) for couples who have been shown to be free of infection by serologic testing (see "Couple Counseling" section).

Outside of these situations, individuals who choose to have sexual relations place themselves and/or their partners at risk of infection. However, the extent of that risk can be decreased by, first, limiting the number of sexual partners. Statistically, the fewer different partners one has, the less likely that one will be exposed. Second, exposure can be further limited by selecting sexual partners at low or no risk of infection, since the prevalence of infection varies greatly by sex, geography, and sex practices (Table 3). Third, the practice of "protective sex" should be able to prevent transmission even if one partner is infected. Epidemiologic studies indicate that sexually acquired HIV infection is due to vaginal or anal intercourse where semen, vaginal fluid, or blood is shared between partners. Yet such studies are not capable of detecting isolated transmission due to other types of sexual activities. The "protective sex" guidelines given here are based on data available as of early 1987. Unfortunately, true efficacy data evaluating these guidelines are not available. Thus, these guidelines must be understood to be interim ones, requiring periodic revision as evaluation data become available.

Protective Sex.—Protective sex refers to sexual activity where no semen, vaginal fluid, or blood is exchanged between partners. Since the skin and oral mucosa appear to be relatively resistant to virus passage, protective sex can involve practices such as kissing (if no oral lesions are present), hugging and caressing, and genital manipulation (if no skin lesions exist). It also can involve vaginal and rectal intercourse, provided a condom is worn at all times. The recommendation for condom use is made because condoms (of high quality[illegible]) have been shown to be effective barriers to viruses, including HIV,[illegible] and preliminary data suggest that sexual partners of infected people may be protected by the use of condoms.[illegible] However, as with the use of condoms for pregnancy prevention, failures can be expected, especially if the condoms are not used consistently and continuously with all sexual partners. The use of nonoxynol 9–containing jelly (sold as over-the-counter spermicide) may be a useful protective adjunct to condoms since this substance has been shown to inactivate HIV and kill lymphocytes.[illegible]

Specific Issues and Problems.—*Homosexual Men.*—Transmission of HIV among homosexual men appears to be due almost exclusively to receptive anal intercourse.[illegible] As of 1987, unprotected receptive anal intercourse with a homosexual or bisexual man carried a considerable risk of infection. The prevalence of infection in this group today is extremely high in most urban areas. Even with profound decreases in the number of sexual partners, the risk of infection in this community remains high because of the present high chance that any single sexual partner is infectious.[illegible]

Considerable confusion has surrounded the issue of what homosexual sex practices are safe. This confusion has been due to several factors: (1) the difficulty in obtaining and interpreting sex practice–specific risk data, (2) discomfort on the part of the heterosexual majority regarding discussions of homosexual sex, and (3) the political vulnerability of government institutions, including public health agencies, to claims of advocating homosexuality if they promulgate safety guidelines for homosexual sex. The result has been either absent or confusing recommendations from traditional public health authorities. In this vacuum, various local groups have made their own, often conflicting, guidelines.

Controversy has surrounded the issue of homosexual bathhouses. Any setting that encourages unsafe sexual practices between individuals will increase the transmission of HIV. As such, those bathhouses that encourage such practices adversely affect AIDS prevention. Yet those bathhouses that encourage protective sex practices can serve as important contact points for educational material and support for protective sex.

The risk of oral-genital sex is apparently low, but, as semen can harbor virus, this practice may carry some risk of infection.

Heterosexual Men and Women.—The frequency with which a person chooses to practice unprotected sex depends on the risk that he or she is willing to take. The current risk of infection of a given heterosexual contact in the United States is low, but infections and AIDS cases are certainly being acquired by heterosexual contact. Logic would dictate that those outside of mutually monogamous relationships who wish to minimize their risk should limit their total number of partners and practice protective sex all of the time.

The efficiency of heterosexual transmission, especially from women to men, continues to be an issue. At least in Africa and in the limited studies in the United States, such transmission certainly occurs. Although the exact risk for a given sexual encounter remains unknown, one must presume that in the United States HIV is transmitted sexually in both directions. Infection with this virus has potentially dire consequences, therefore, sexual partners should carefully weigh the risks of unprotected sexual encounters outside of mutually monogamous relationships.

Prostitutes are a major source of infection in central Africa[illegible] and probably in some European countries. Some may have moderate to high rates of infection in the United States[illegible]—especially those who are users of IV drugs.

As with homosexual men, the risk associated with oral-genital sex is apparently low, but, as semen and vaginal secretions can harbor virus, this practice may carry some risk of infection.

Blood and Blood Products

Infection from donated blood and blood products could be prevented if material from infected donors could be identified and discarded before administration. The Food and Drug Administration has instituted regulations and guidelines to protect blood and blood products from HIV infection. These include (1) self-deferral of donors belonging to high-risk groups (instituted in March 1983); (2) testing of all blood and plasma for HIV antibodies and discarding units that test positive (instituted in April 1985); and (3) heat inactivation of products, like factor VIII, that can tolerate heating (initiated in 1984 for factor VIII). These precautions should virtually eliminate the risk of HIV infection from the use of these products. Products derived from plasma that have steps in their manufacture that physically remove and/or chemically inactivate virus, like immunoglobulin and hepatitis B vaccine, have always been considered safe,[illegible] and all of the laboratory and epidemiologic data collected on these products in recent years have confirmed their safety.[illegible]

Needle and Syringe Sharing

Needle- and syringe-associated HIV infection could be avoided if unsterilized injection paraphernalia were not shared among individuals. The message for AIDS prevention is obvious: stop the use of IV drugs, or, at a minimum, eliminate sharing of unsterilized injection paraphernalia. For some addicted IV drug abusers, this is difficult or impossible, and other options, such as disinfection with readily available agents (eg, bleach), should be advocated. Furthermore, addicted persons who desire to enter rehabilitation programs should be encouraged and allowed to do so. Outside the addicted population, there is evidence that substantial numbers of persons experiment with drugs. Educational programs directed toward teenagers, drug-using communities, and staffs of drug clinics need to emphasize the potential dangers of sharing drug paraphernalia.

Specific Issues and Problems.—Intravenous drug users often have little foresighted health interest and, thus, may prove to be the greatest challenge for instilling behavior change.

Intravenous drug use is illegal throughout the United States. However, systems have been designed to deal with addicts in medical facilities without threatened incarceration.

Discussions of drug use and, more specifically, of means by which to render drug use safer have been interpreted by some as an advocation of drug use. As a result, many health educators have avoided the subject.

Intravenous drug abusers often do not engender sympathy from those responsible for providing funding for intervention programs or those responsible for public health.

Slots for drug treatment clinics are often not available, preventing those who want to stop using IV drugs from doing so.

Intravenous drug abusers, if HIV transmission persists, will likely serve as a major entree of the virus into a segment of the heterosexual community, most prominently in the urban poor communities. Indeed, an early, aggressive prevention effort is required to prevent further extension of this virus into social/ethnic minority urban communities.

Provision of sterile needles and syringes to drug users is a controversial, yet possibly effective, control modality that requires further evaluation.

Drug use, in a broad sense, affects other AIDS prevention activities, especially protective sex. The use of drugs in association with sexual practices is prevalent in many communities, including the homosexual male community.

Perinatal Transmission

Mother-to-infant HIV infection could be avoided if infected women would not become pregnant. Because of the potential high risk of infant infection and the preliminary clinical findings that pregnancy itself may accelerate the development of AIDS, it seems reasonable at this time to recommend that infected women postpone pregnancy until more is known about the risks and prevention of perinatal infection.[illegible] The question is then, how can infected women be identified? With the low infection rates in most female populations of childbearing age, general, routine screening is not warranted at this time. However, there is general agreement that women who are in high-risk groups (IV drug users, prostitutes, women with multiple sexually transmitted infections, women from HIV endemic areas, or sexual contacts of high-risk-group men) should be screened and counseled.[illegible]

THE ROLE OF CONTACT TRACING/NOTIFICATION

Purpose of Tracing

The purpose of tracing sexual or needle-sharing contacts of infected people is to trace the chain of transmission to its terminus. At that point there may be an infected person having risk-provoking contact with another susceptible person or persons. With appropriate education and motivation of the infected and susceptible contacts, further transmission can be prevented. The specific guidelines to be given to the interfacing contacts would be the same risk-specific ones presented above (Table 3).

Specific Issues and Problems

Although contact tracing/notification could be useful for interrupting chains of HIV transmission, the cost of finding, testing, and counseling individual sexual or needle-sharing contacts of infected individuals is considerable. Even under the best of circumstances, the task is expensive, but often with individuals who have the largest numbers of contacts, the identifying information on contacts may be limited, and the task becomes even greater. Thus, for these "fast lane" individuals, the assumption must be made that all within the group should come in for testing and counseling. For persons with fewer contacts (including homosexual men and IV drug users in lower-risk settings and especially women in the childbearing age) whose locating information may be more readily available, more intensive efforts, both by physicians and health departments, is justifiable.

There is concern, especially in the homosexual community, regarding the confidentiality of contact tracing/notification. Few dispute the need or the potential beneficial effect of referring contacts for testing and education. The concern rests with individuals who, being uncomfortable with notifying their own contacts, ask the physician or health department to do the tracing and volunteer the names to these third parties. This is a delicate situation, but one that has been successfully addressed for decades in public health clinics. For those physicians not comfortable or trained in contact tracing, referral to highly experienced health department staff should be available.

Table 3 —Prevalence of HIV Infection (Antibody) in Various US Population Groups (1985-1986)*

Group	% Infected
Homosexual men	
STD clinic (San Francisco)	72
Random (San Francisco)	49
IV drug users	
New York City	59
San Francisco	9
Hemophiliacs (factor VIII)	74
Female prostitutes	
Seattle	5
Miami	40
Haitians	
New York City	4
Miami	8
Women	
Blood donors (Atlanta)	0.01
Military applicants	0.06

*Data from *Morbidity and Mortality Weekly Report*.[65,81] HIV indicates human immunodeficiency virus; STD, sexually transmitted disease; IV, intravenous.

THE ROLE OF SEROLOGIC TESTING

The serologic test for HIV antibody is potentially an important tool for prevention. There has been considerable misunderstanding and controversy in the past about the value of serologic testing, the accuracy of the test, and the fears of violation of confidentiality.[70] However, this controversy appears to be declining as the value and accuracy of the test are documented and as assurances of confidentiality are maintained and strengthened. Indeed, encouragement of serologic testing has been recommended[71] for several reasons, and they are outlined below according to the target groups involved.

Infected Persons

If all infected (antibody-positive) individuals could be identified through voluntary and confidential testing programs and if these individuals could be counseled on ways to prevent exposure to others, then a major step toward decreasing AIDS could be achieved. Infected men and women could be advised of their risk to sexual partners or those exposed to their blood. Infected women could be advised to avoid pregnancy. Along with this beneficial preventive effect, serologically identifying infected persons could have significant clinical benefit to individual patients. The knowledge by the patient and physician regarding infection by this virus could lead to earlier recognition and treatment of life-threatening opportunistic infections, especially *Pneumocystis carinii* pneumonia. Infected patients who are tuberculin test positive could receive early prophylaxis, and parents of infected children could be informed about the relative contraindication of live viral or bacterial vaccines. Furthermore, because (at least in the laboratory) immunologic stimulation of lymphocytes accelerates viral replication,[6] exposure to foreign antigens may accelerate disease progression in humans. Thus, individuals who discover that they have been infected with HIV should be encouraged to decrease their antigen exposure by decreasing their number of sexual and IV drug encounters.

Susceptible Persons

If uninfected (antibody-negative) individuals at increased risk of infection could be identified and counseled, their risk-taking behavior might decrease substantially. The value of one-on-one counseling centered around knowledge of one's serologic status can enhance the effects of education programs on behavior modification. For example, serologic testing, combined with counseling, can have a profound effect on encouraging low-risk sexual practices among some[72] but not all[73,74] homosexual men.

Couple Counseling

The serologic test also has a role for couples of which one partner has been possibly exposed. If individuals desire to have unprotected sex and one or both have been at any risk of infection, it is reasonable to test the at-risk individual for HIV antibodies. If he or she has a negative result and has not been at any continued risk of exposure over the past six months, then one can presume the absence of infection. If a seronegative individual has been possibly exposed in the past six months, then a second test six months after the last possible exposure is required before infection can be confidently ruled out. For greatest safety, protective sex should be practiced during this interim period. A similar approach may be useful for women who may have been exposed to an infected person in the past and now want to become pregnant. Serologic testing with follow-up testing in six months, where indicated, should be helpful in giving advice to such persons.

Evaluation

Serologic testing is also an important tool for evaluating the effect of any prevention program. For individuals, physicians, and public health practitioners, periodic repeated testing of antibody-negative individuals is the only accurate measurement of the success of their prevention efforts. Uninfected persons, especially those with presumed or known continuing exposure, need periodic reassurance that their efforts to remain uninfected have been successful. Moreover, physicians and public health practitioners providing advice and guidelines to at-risk individuals need assurance that the provided guidelines have been effective.

Testing Facilities

The facilities for free or low-cost and confidential testing, together with risk-reduction counseling, have been provided by the national alternate test site program. Testing is also available through many physicians' offices. The use of these facilities by at-risk individuals should be encouraged by all. In addition to patient-initiated serologic testing, physicians should encourage at-risk individuals who may benefit from testing to be serologically tested—either in their offices or at public facilities. Specific efforts should be directed at the highest-risk groups: homosexual or bisexual men, prostitutes, heterosexual men and women who have multiple sexual partners, patients with sexually transmitted diseases, patients known to use IV drugs, and patients from HIV-endemic areas such as Haiti and central Africa.

In summary, serologic testing allows for knowledgeable clinical and preventive counseling of patients, including medical evaluation and early intervention, personal counseling regarding decreasing transmission, contact tracing/notification, and counseling to prevent perinatal transmission.

Specific Issues and Problems

For most individuals the process of testing is a stressful one. To maximize the use and benefit of test-linked counseling, the staff of these facilities must be sensitive to the stresses of the individuals and provide counseling and, where appropriate, referral.

DISEASE AND INFECTION MONITORING (SURVEILLANCE)

Conditions related to HIV are of a wide clinical spectrum, ranging from asymptomatic infections, various AIDS-related conditions, frank AIDS, and primary peripheral and central neurologic conditions. Surveillance (the collection, analysis, and dissemination of data relevant for prevention or control) for clinical AIDS has formed the foundation for our current understanding of this newly imported disease, and physicians should always report cases according to local requirements. But with the long incubation period after infection before AIDS develops, surveillance for clinical AIDS is a rather insensitive and delayed indicator of HIV infections. Thus, the future of public health surveillance will have to rely more heavily on serologic surveillance Ideally, the serologic status of members of all of the major risk groups would be known, along with the annual seroconversion rates and reasons for seroconversion. Unfortunately, because of the expense of collecting such information and because of fears of confidentiality breaches, such data exist for only limited populations studied in research settings. At a minimum, systems should be devised to monitor the rates of infection in selected groups ranging from low-risk individuals (eg, blood donors) to high-risk individuals (eg, homosexual men patients at methadone clinics, sexually transmitted disease clinic patients, etc). If the ideal situation of absolute confidentiality cannot be assured, periodic testing of serum unlinked to personal identifiers is an alternative. Additional useful data are potentially available from the military's nationwide recruit testing program and the proposed sentinel hospitalized-patient (without personal identifiers) testing program of the Centers for Disease Control, Atlanta.

Specific Issues and Problems

Some physicians, to protect the confidentiality of patients and families, resist reporting cases or including AIDS on death certificates. The resulting reporting errors could markedly affect future surveillance, especially in regard to the occurrence in suburban and rural areas. Sensitive situations can generally be worked out with local health departments on an individual basis.

PHYSICIAN, PUBLIC HEALTH, BUSINESS, AND COMMUNITY ROLES IN AIDS PREVENTION

Physician

The physician's role in AIDS prevention is critical. At a minimum, the physician must understand the myriad symptoms of HIV-related diseases and provide effective medical treatment and support for the individual and the family. In addition, the physician must take a major lead position regarding prevention. Specifically, nonjudgmental discussions of sexual orientation, sexual activities, IV drug use, and ways to prevent AIDS should become standard parts of medical care. These should include (where appropriate) recommendations for serologic testing, protective sex guidelines, and contact tracing/notification of sexual and IV drug-sharing contacts. As part of this process, physicians should become well versed in HIV transmission so that individual and community questions regarding appropriate preventive practices can be knowledgeably answered to maximize preventive intervention and minimize ill-based and extremist overreaction.

Public Health

The central role that federal, state, and city/county health departments and laboratories traditionally have held in communicable disease control will have to continue for AIDS. The necessities of infection and disease monitoring, educating physicians and the public about AIDS, establishing appropriate guidelines for prevention, and providing the needed personnel and resources for education, counseling, testing, and contact tracing/notification will be large tasks for public health agencies, especially in these times of constrained funding.

Business

The impact of AIDS on the private sector is large and growing The direct medical costs, the benefit support costs, and the general social upheaval (due primarily to unfounded concerns about the possibility of casual-contact transmission) will continue to take a major toll within the business community. Much of this toll is preventable, including that related to unfounded fears of infection. Indeed, the workplace could serve as an important access point to convey the essentials of AIDS prevention. After all, working adults have been the major target of this virus. Education programs sponsored by businesses directed toward all sexually active employees, regardless of sexual preference, together with information on the risks of needle sharing, could have a major impact on HIV transmission. Furthermore, support by the business community for funding of public AIDS prevention programs could prove invaluable in stimulating the traditionally slow government funding process so that more extensive AIDS prevention programs could be started without undue delay.

Community

The need for rational community programs for AIDS prevention based on facts rather than fears is urgent. Too often schools, religious organizations, and other community groups have been reticent to discuss, or even obstructed from discussing, ways to prevent the sexual or needle-borne transmission of HIV for fear of seeming to support sex and drug use. Such issues are difficult, but denial of real-life practices can serve only to extend further this already deadly epidemic. Community groups and public media are essential for spreading the rather simple words of AIDS prevention. In addition, together with business, their support of health department efforts, their aid in the defense against extremist measures, and their support for additional resource allocations for AIDS prevention are essential.

In summary, the concerted efforts of physicians, businesses, and community groups and public media, together with provision of up-to-date educational materials and consistent prevention messages issued by health departments, are essential to interrupt transmission of this extremely severe virus infection effectively.

SOCIAL ISSUES AND CONFIDENTIALITY

Quarantine/Isolation

The purpose of AIDS prevention programs is to interrupt the transmission of HIV in a manner that will minimize social disruption and maximize individual freedom. The issue of quarantine (this term will be used interchangeably with isolation or enforced isolation) needs to be discussed openly because of the concerns expressed by at-risk groups, especially the homosexual and hemophiliac communities, and because some ill-informed political groups have called for extreme measures (eg, quarantine) to control AIDS. Many of these overreactive proposals have been due to unbalanced information that, although appropriately stressing the dangers of HIV infection, has inappropriately stressed the ease of acquisition. In the hospital setting, recommendations are that blood and secretion precautions (a form of medical isolation) be taken for persons known or suspected to be infected with blood-borne agents such as hepatitis B virus or HIV. But within the general community, there has never been any official public health recommendation or movement toward the isolation or quarantine of carriers of these difficult-to-transmit agents. Quarantine has a limited role in the control of some communicable diseases, but there is little or no role for it in the prevention of AIDS. As mentioned above, except for perinatal infection and (in the past) blood product–associated infection, HIV is transmitted almost exclusively between consenting adults, both of whom have some choice regarding the AIDS risks they are willing to take. Thus, transmission of this virus in our society is preventable by individual action, not government-imposed isolation. The threat of quarantine hinders AIDS prevention. It turns a nonissue into a wedge between advocates of prevention and the groups at risk for AIDS.

The issue of mass quarantine aside, what should be done with the uncooperative infected person who continues to expose individuals through sexual intercourse or needle sharing? For example, what about the infected female or male prostitute who continues to ply the streets for business? These are difficult issues. State laws generally forbid one from knowingly exposing others to infectious diseases, and local or state health officers generally have authority (following observance of due process) to incarcerate noncompliant individuals. In some situations, incarceration may be necessary, but in most situations there are *two* persons involved in the transmission of HIV. Thus, it could be said for the example given above that the client of the prostitute is "volunteering" for infection. The major task ahead is to get accurate information out to the public so that they can make informed choices. Considering the danger of this virus, most persons will presumably take the personal steps necessary to avoid infection.

Patient–Physician–Public Health–Community Relations

For physicians and public health workers to effect risk-reducing behavior changes in individuals, considerable patient trust is necessary, both to initiate contact and to seek advice and follow guidance. After all, the behavior changes sought to decrease AIDS risk involve the most personal of behaviors. To stimulate individuals to take responsibility for themselves and make the necessary risk-reducing changes is often difficult and requires a good deal of trust and understanding from both the patient and the health worker. This relationship can be seriously jeopardized if the individual in need of guidance is frightened away from professional services by hostile threats of reprisals (eg, quarantine).

Confidentiality

Maintenance of confidentiality is central to and of paramount importance for the control of AIDS. Information regarding infection with a deadly virus, sexual activity, sexual contacts (both within and without primary relationships), and the illegal use of IV drugs and diagnostic information regarding AIDS-related diseases are sensitive issues that, if released by the patient or by someone involved in health care, could adversely affect a patient's personal and professional life.

Confidentiality has always been a strictly observed principle in medicine and public health. Sensitive topics have always by necessity been a routine part of interviews and records in these fields. However, for AIDS, because of the social disdain toward the two highest-risk groups, and the illegal status of IV drug use, and the numerous antisodomy laws, even stricter assurances are required. In some states, like California, legislation has been passed to strengthen these confidentiality assurances. In some situations such laws have caused problems and have prevented essential communications between physicians and practitioners of public health. But this is an evolving field and, as such, there is constant change and adjustment. The public's confidence in the public and private sectors' protection of their privacy depends on repeated examples and public stands taken by all involved in AIDS treatment and prevention. With positive examples many of the difficulties centered around serologic testing and contact tracing/notification will abate.

Insurance

Insurance companies are considering requiring serologic testing for selected applicants for life and individual health policies. In areas where the use of HIV testing for this purpose is not allowed, surrogate tests such as lymphocyte subsets are being considered. This is a sensitive issue in that identification of infection can be used to infer life-styles unpopular with some employers and coworkers. Possible solutions, including insurance pools that cover costs of HIV-related conditions, need to be considered nationally or regionally.

INSTITUTIONAL ISSUES

As repeatedly stressed in this review, HIV transmission has essentially occurred only through sexual encounters, blood/needle sharing, or from mothers to their infected infants at or near birth. Despite these observations, there has been much concern regarding "casual" transmission in public places such as offices, public buildings, and schools. In some situations, a combination of misinformation and a desire to structure "no-risk" settings has resulted in considerable social disruption, such as exclusion of children with AIDS from school. Future approaches will have to take into account existing information and move away from these extreme views. These major issues will be addressed by institutional category.

Public Buildings, Offices, Schools, and Mental Institutions

No risk of transmission has been documented (either by serologic studies or investigation of AIDS cases) outside of established modes. Indeed, aside from the possible spread from brother to brother,[illegible] no transmission has occurred (outside of sexual contact) in households having infected individuals[illegible] and no transmission has occurred from patients to their nurses (except by needle or open wound exposure) in hospitals. If no transmission has occurred in these settings, which have traditionally been at-risk settings for similarly transmitted agents like hepatitis B virus,[illegible] then one can be confident that no HIV transmission occurs in any more casual settings like offices and public facilities. The purveyors of health information need to maintain a high level of public knowledge regarding the latest findings of HIV transmission so that unfounded anxieties can be allayed and appropriate actions can be taken.

Schools are of special note because, in the past, they have served as a battleground over the issue of excluding pediatric patients with AIDS. More information is now available, specifically regarding the lack of transmission from children to their household contacts, including those with whom they have shared toothbrushes, towels, etc[illegible]; thus, schools, having far less intimate contact than households, become even more remote prospects for transmission. With these data, the Centers for Disease Control have promulgated guidelines for the handling of infected children in schools.[illegible]

The only remaining area of concern is children who, because of age or mental incompetence, do not have control of their bodily functions. Although these children are very unlikely to be at risk of HIV transmission, previous experience with a variety of infectious diseases in facilities for the mentally retarded and day care centers requires some concern for these areas. Before firm recommendations can be made for these latter facilities, further study is required.

Prisons

Especially on the east coast of the United States,[77] prisons have had a considerable number of AIDS cases. The acquisition of infection for these cases has, by history, been due to high-risk activity (primarily IV drug use) before entering prison. Yet, risk-provoking exposures such as percutaneous injections and homosexual sex do take place in prisons, and, in some instances, these exposures occur in involuntary settings. The provision of AIDS prevention information and the motivation of all prisoners to avoid infection are essential. The question is, can education alone prevent high-risk exposures, or will screening of prisoners and the provision of separate housing facilities for persons with positive and negative HIV antibody findings have to be considered? Because of the potential expense and the difficulty in implementing the latter option, and the lack of data to suggest a high risk of HIV transmission in prisons, further study of this situation is clearly justified before objective decisions can be made.[illegible]

Bathhouses

Business establishments such as bathhouses, bars, and adult book stores, where multiple, usually anonymous sexual encounters take place among a male homosexual clientele, have facilitated the spread of HIV infections. Public health agencies in some areas, such as San Francisco and New York, have attempted to close these establishments. Only a few such closings have taken place, and they have, to a great extent, been largely symbolic to discourage the use of such facilities for unsafe sexual activities. The closing of such establishments should be required if unsafe sexual activities cannot be eliminated. However, prior to compulsory closing, some type of regulatory inspection of these establishments should be carried out to maintain environmental and sanitation standards (such as improved lighting and removal of doors to private rooms) to discourage unsafe sexual contacts.

CONCLUSION

Human immunodeficiency virus is a dangerous infectious agent that spreads effectively only through the sharing of blood, through sexual intercourse, and from infected mothers to their infants. The combined use of education/motivation/skill building, serologic screening, and contact tracing/notification could eliminate or substantially reduce at-risk behaviors and infection. The accomplishment of this reduction requires a considerable effort by physicians, public health practitioners, business, and community organizations to get across the relatively simple AIDS prevention messages. Only through a concerted effort by all of these groups will the reluctance of individuals and society to deal with the difficult issues inherent in AIDS prevention and control be overcome. The eventual extent of HIV transmission and the resulting morbidity and mortality will be determined by how well we as a society can design and implement a concerted AIDS prevention effort and how we as individuals heed the messages of that prevention effort and take personal responsibility to protect ourselves. It is clear that if a total effort is not developed and sustained, the impact on present-day America will be protean, and subsequent generations of Americans will inherit an expanding rather than a confined infectious disease problem.

Since the preparation of this article, two relevant documents have been released: the Surgeon General's report on AIDS[illegible] and the Institute of Medicine/National Academy of Sciences report entitled *Confronting AIDS: Directions for Public Health, Health Care and Research.*[illegible]

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PEDIATRIC INFECTIOUS DISEASE

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AIDS in children: a review of the clinical, epidemiologic and public health aspects

MARTHA F. ROGERS, MD

BACKGROUND

In 1981 an epidemic of a severe form of acquired immune deficiency, now known as acquired immunodeficiency syndrome (AIDS), began in homosexual men and intravenous drug abusers in New York City, San Francisco and Los Angeles.[1] Since that time over 7000 cases from 45 states and 32 foreign countries have been reported to the Centers for Disease Control (CDC). The disease affects primarily the cellular immune system and in its severe form results in repeated opportunistic infections and malignancies.

To date 107 cases of AIDS in children and adolescents have been reported to CDC. Children with AIDS present a number of difficult problems to the pediatrician regarding diagnosis, management and psychosocial issues. This paper reviews the clinical, epidemiologic and public health aspects of AIDS in the pediatric population.

ETIOLOGY

Recent evidence strongly implicates a retrovirus as the cause of AIDS. Two prototype viruses were initially identified independently by investigators at the Institut Pasteur in France[2] and at the National Cancer Institute in the United States.[3] Evidence indicates that these two viruses are the same.

In 1983 investigators at the Institut Pasteur in Paris isolated a retrovirus from a homosexual man with lymphadenopathy syndrome, a syndrome thought to be a mild form of or precursor to AIDS.[2] This virus, morphologically different from the known human retroviruses, was termed the lymphadenopathy-associated virus (LAV). This virus was subsequently isolated from other AIDS patients, including one patient with transfusion-associated AIDS and one of the donors of the transfused blood.[4] A seroepidemiologic study showed that antibody to this virus was present in more than 70% of patients with AIDS or with symptoms strongly suggestive of AIDS, in only 1% of healthy blood donors and in none of their patients with congenital immunodeficiencies.[5]

In 1984 investigators at the National Institutes of Health, United States, isolated a retrovirus, termed the human T-lymphotrophic retrovirus, type III (HTLV III), from a number of patients with AIDS, from patients with symptoms strongly suggestive of AIDS and from asymptomatic homosexual men.[3] The virus was not isolated from healthy heterosexual subjects. A seroepidemiologic study found antibody to the retrovirus in similar populations.[6]

Retroviruses are RNA viruses which contain an enzyme, reverse transcriptase, that transcribes DNA from RNA, a process used in the replication of these viruses. Although retroviruses infect many animal species, only two other human retroviruses are known: (1) human T cell leukemia/lymphoma virus (HTLV) type I which has been isolated from patients with malignancies of the thymus-derived lymphocytes[7] and (2) HTLV type II which has been isolated from a patient with a T cell variant of hairy cell leukemia.[8]

The AIDS retrovirus, like other human retroviruses, primarily infects the lymphocytes derived from the thymus (T lymphocytes), which are responsible for cellular immunity. The AIDS virus preferentially infects the subset of T lymphocytes known as helper T lymphocytes which augment the immune response. The subset of T lymphocytes which suppresses the immune response, the suppressor T lymphocytes, is relatively spared and outnumbers the helper T cells. The bone marrow-derived lymphocytes (B lymphocytes), which are responsible for antibody production, are also relatively spared.

CASE DEFINITION

The CDC case definition for AIDS, developed before the discovery of the etiology of AIDS, is based on clinical signs and symptoms. A case is defined as a child diagnosed as having an opportunistic infection

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TABLE 1

Diseases accepted by CDC as indicative of underlying cellular immunodeficiency

- Protozoal and helminthic infections
  - Cryptosporidiozis duration >1 month
  - *Pneumocystis carinii* pneumonia
  - Strongyloidosis*
  - Toxoplasmosis*
- Viral infections
  - Cytomegalovirus disseminated infection with onset >6 months of age
  - Herpes simplex virus, chronic or disseminated infection with onset >1 month of age
  - Progressive multifocal leukoencephalopathy
- Fungal infections
  - Candidiasis, esophageal
  - Crytococcosis, central nervous system or disseminated infection
- Bacterial infections
  - *Mycobacterium avium*, disseminated infection
- Cancer
  - Kaposi's sarcoma
  - Lymphoma limited to the brain

* Pulmonary, central nervous system or disseminated infection

or malignancy (Table 1) indicating an underlying cellular immunodeficiency. Other causes of immunodeficiency such as congenital immunodeficiencies, congenital infections, medications, lymphoreticular malignancy and starvation must be ruled out. Because this definition requires the presence of an opportunistic infection or malignancy, the cases of AIDS retrovirus infection reported to CDC are the most severe. Less severe forms of the illness appear to occur. Symptoms associated with AIDS such as generalized lymphadenopathy, chronic diarrhea, weight loss or failure to thrive, recurrent infections, persistent oral candidiasis, interstitial pneumonitis and hepatosplenomegaly have occurred in patients belonging to high risk groups. This constellation of symptoms has been called AIDS-related complex and has been used to describe patients in high risk groups who have symptoms that are associated with AIDS but who have not developed an opportunistic infection or malignancy. Since development of the serologic tests for measuring antibody to the AIDS virus, antibody to HTLV III/LAV has been found in patients with AIDS-related complex and asymptomatic members of high risk groups.[9] HTLV III/LAV has been isolated from these asymptomatic seropositive persons suggesting that a chronic carrier state can exist. In a recently reported study virus was also isolated from four persons who were seronegative.[10] Long term follow-up of these individuals is needed to clarify the relationship between antigen and antibody production and clinical symptoms.

PEDIATRIC HIGH RISK GROUPS AND ROUTES OF TRANSMISSION

In adults and adolescents over 95% of cases have occurred in persons belonging to six high risk groups: Group 1, homosexual or bisexual men; Group 2, intravenous drug abusers; Group 3, Haitians; Group 4, hemophiliacs, Group 5, persons receiving blood or blood products, and Group 6, the sexual partners of infected persons This epidemiologic evidence indicates that, in adults and adolescents, AIDS is transmitted through sexual contact (both hetero- and homosexual contact) or through parenteral exposures such as the sharing of needles used for injecting illicit drugs or through blood transfusions.

In younger children two risk factors are primarily associated with infection: (1) receiving blood or blood products; and (2) birth to a mother who has AIDS, is a member of a high risk group or is a sexual partner of a member of a high risk group (Fig 1). The route of transmission in those children born to high risk parents is unknown, but the retrovirus may be acquired *in utero*, from infective maternal blood at the time of birth or postnatally. Data from cases reported to CDC suggest that children born to high risk parents may acquire infection *in utero*. The median time interval between birth and onset of symptoms in children of high risk parents is 4 months. This is shorter than the median time interval of transfusion-associated illness in which the time between transfusion and onset of symptoms is 8 months.

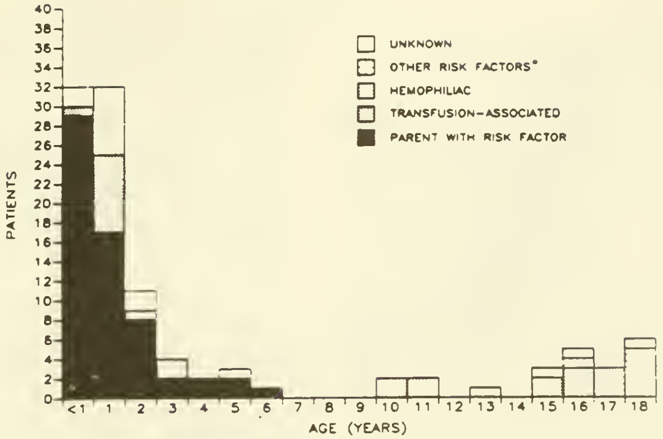
Postnatal transmission, through infected breast milk or close contact between the mother and baby, could theoretically occur. However, none of the 7408 cases reported to the CDC as of December 13, 1984, has occurred in individuals who were household contacts (nonsexual) of other AIDS patients, suggesting that transmission through casual person-to-person contact, if it occurs, is rare. All the patients reported to CDC with no identifiable risk of exposure deny contact with a known AIDS patient. Breast milk from infected mothers has not been cultured.

INCUBATION PERIOD

The incubation period for this virus appears to be relatively long. Based on cases of transfusion-associated AIDS in adults reported to CDC, the period between transfusion (infection with the virus) and onset of symptoms ranged from 1 month to 5 years (median, 28 months). In the 12 children with transfusion-associated AIDS, this time period was somewhat shorter, ranging from 1 month to 2 years, 5 months (median, 8 months). The reason for the shorter incubation period in children compared with adults is not clear. All 12 children were neonates, who may be at increased risk due to an immature immune system.

CLINICAL COURSE

Prodrome. Before development of opportunistic infections and malignancies, adolescent and adult patients usually experience a prodrome characterized by an insidious onset of weight loss; fever; malaise; night sweats; chronic or recurrent unexplained diarrhea; fatigue; generalized lymphadenopathy; arthralgias or



*HOMO/BISEXUAL, SEX CONTACT OF PERSON WITH RISK FACTOR, HAITIAN ORIGIN, IV DRUG ABUSER

FIG. 1 Pediatric patients with acquired immunodeficiency syndrome, by age at time of diagnosis of opportunistic infection or malignancy and associated risk factors

myalgias and oral candidiasis. The prodrome may last from weeks to months.

Infants who are infected with HTLV III/LAV in the neonatal period usually develop signs and symptoms before 1 year of age, typically failure to thrive, recurrent or persistent thrush, chronic interstitial pneumonitis, hepatosplenomegaly, chronic or recurrent diarrhea, lymphadenopathy and recurrent severe bacterial infections such as sepsis and meningitis. A relatively uncommon finding is recurrent enlargement of the parotid glands. These prodromal signs and symptoms, as in adults, can last from weeks to months before development of an opportunistic infection or malignancy.

Opportunistic diseases. The most common diseases seen in patients with AIDS are viral, fungal and parasitic opportunistic infections and malignancies. *Pneumocystis carinii* pneumonia is the most common infection, occurring in 70% of pediatric patients reported to the CDC. The most common malignancy seen is an aggressive form of Kaposi's sarcoma occurring primarily in homosexual men, but it has been reported in children. Non-Hodgkins lymphomas also occur.

Laboratory findings. Laboratory abnormalities characteristic of AIDS include lymphopenia, specifically a decrease in the T helper lymphocytes, resulting in a reversal of the ratio of T helper cells (OKT8+, Leu3+) to T suppressor cells (OKT4+, Leu2+). Lymphocyte function is also abnormal as measured by a markedly depressed response to mitogens such as phytohemagglutinin and concanavalin A and to antigens. Most patients also react poorly to skin tests with recall antigens. Serum immunoglobulin levels are normal or more commonly increased.

DIAGNOSIS

AIDS must be differentiated from other causes of immune deficiency such as treatment with immunosuppressive drugs, congenital immunodeficiencies, congenital infections and starvation. A careful history and physical examination should rule out immunodeficiency secondary to recent oral or parenteral use of steroids or cytotoxic agents and starvation. Malignancies that are associated with immunodeficiency, particularly lymphomas, must be considered. Congenital infections and immunodeficiencies may be more difficult to differentiate.

Cellular immunodeficiency can be associated with some congenital infections, such as cytomegalovirus[11] infection or rubella.[12] However, this immunodeficiency is temporary and is usually less severe than that associated with AIDS. Unlike most congenital infections, symptoms associated with AIDS do not usually occur in the neonatal period, and developmental defects such as cardiac abnormalities have not been reported in children with AIDS. Infants with AIDS can acquire infections such as cytomegalovirus and toxoplasmosis as a result of AIDS, but acquisition is usually not in the neonatal period, and these infections are generally much more severe than acquired infection in the immunocompetent child.

Congenital immunodeficiencies to be considered include severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome, ataxia-telangiectasia, graft *versus* host disease, neutropenia, neutrophil function abnormality, agammaglobulinemia and hypogammaglobulinemia with elevated IgM. Unlike patients with severe combined immunodeficiency and immunoglobulin deficiencies, patients with AIDS usually have markedly elevated immunoglobulins. Unlike children with DiGeorge syndrome, children with AIDS have normal facies and do not have hypocalcemic tetany. Although thrombocytopenia may be seen in children with AIDS, bleeding episodes do not usually occur as with Wiskott-Aldrich syndrome. Wiskott-Aldrich syndrome, an X linked recessive disease, occurs almost exclusively in boys, whereas about 40% of children with AIDS are girls. AIDS may be differentiated from neutrophil disorders by its primary effect on lymphocytes rather than on granulocytes. Ataxia is not a common feature of AIDS.

TREATMENT

Although some therapies have resulted in temporary improvement and prolonged survival, to date no effective therapy for AIDS exists. Intravenous gammaglobulin is being used in some centers with variable success in preventing recurrent episodes of sepsis and meningitis.[13] Bone marrow transplantation and lymphocyte transfusion have resulted in partial immunologic reconstitution in some cases, but without clinical improvement.[14] Recombinant alpha-2-interferon therapy has been reported to reduce the size of the lesions of Kaposi's sarcoma in some cases but did not produce changes in immunologic characteristics.[15] Suramin, an inhibitor of reverse transcriptase *in vitro*,[16] and ribavirin, a reported suppressor of replication of LAV in culture,[17] are being assessed. Early diagnosis and treatment of opportunistic infections and malignancies associated with AIDS may prolong survival. Careful attention to the nutritional and the emotional needs of patients and their families is helpful.

PROGNOSIS

The prognosis for HTLV III/LAV-infected patients who develop opportunistic infections or malignancies is poor. Of the 7408 patients reported to the CDC since the epidemic began, over 40% have died. Of those patients diagnosed prior to 1982, over 80% have died. Of the 103 children age 18 years or younger with outcome reported to the CDC, 65% have died. Although the long term prognosis of infection with HTLV III/LAV has not been determined, a few longitudinal studies of high risk patients with symptoms of AIDS but without opportunistic infections have revealed that as many as 20% develop AIDS within 3 years of onset of symptoms[18] and up to 50% of adult patients with oral candidiasis develop AIDS.[19] Similar longitudinal studies in children have not been reported.

OCCURRENCE

Of the 7408 cases of AIDS reported to CDC as of December, 1984, 107 (1.4%) were in children and adolescents 18 years of age or younger. The number of cases of AIDS in the pediatric population has been steadily increasing since diagnosis in 1979 of the earliest case reported to CDC (Fig. 2). The apparent decrease in cases reported in the latter half of 1984 probably reflects the lag time between diagnosis and receipt of case reports.

Of the 107 children, 71 (66%) had *P. carinii* pneumonia, 5 (5%) had Kaposi's sarcoma, 2 (2%) had both and 29 (27%) had some other opportunistic infection. There were 1.6 times as many cases in males (66) as in females (41). A greater proportion of cases occurred in blacks (54%) and Hispanics (19%) than in whites (27%). The 107 cases were reported from 18 states and Puerto Rico with 79% residing in New York, New Jersey, Florida or California.

The majority of pediatric patients with AIDS were preschool-aged children (Fig. 1). Of the 107 children and adolescents with AIDS, 84 (79%) were younger than 6 years of age at the time of diagnosis of AIDS. All of these children, in whom investigations have been completed, acquired AIDS either from a blood transfusion (12 children) or because they were born to a mother who had AIDS, was a member of a high risk group or was a sexual partner of someone in a high risk group (60 children).

PREVENTION

Since a large proportion of children with AIDS acquire the disease through exposure to their parents, prevention of AIDS in adults would be expected to prevent cases in children as well. Behavior modification in adults and adolescents such as reduction of the number of sexual partners, especially those in high risk groups, participation in drug rehabilitation programs and avoiding the use of nonsterile needles may help reduce cases.

Prevention of congenital cases through birth control and abortion are also important; however, the risk of AIDS in infants born to infected mothers is unknown. In 11 mothers who had already delivered one child with AIDS, 12 subsequent pregnancies produced 4 affected infants, suggesting that the risk of transmission of the agent is a continuing one and that each pregnancy may be at high risk for infection.[20] Infected mothers are often asymptomatic before and during the pregnancy and at the time of birth, making any intervention such as avoidance of pregnancy or abortion impossible.

Prevention of AIDS through reduction of infected blood and blood products would also significantly re-

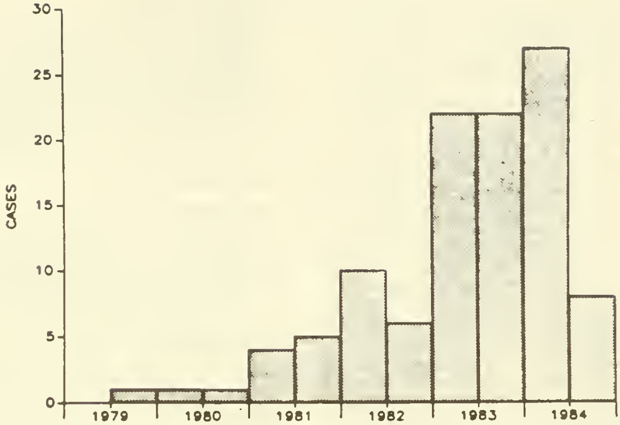


FIG. 2. Cases of acquired immunodeficiency syndrome in children 18 years of age or younger, by half-year of diagnosis, 1979 to 1984

duce cases in children. Cases in hemophiliacs and children receiving transfusions account for 21% of cases in children reported to CDC. The United States Public Health Service currently recommends that persons belonging to high risk groups refrain from donating blood. Blood banks anticipate being able to screen blood for antibody to HTLV III/LAV which is expected to eliminate 95% of infected blood. However, because of the long incubation period of the virus, cases attributable to blood transfusions will continue to occur.

Heat treatment of Factor VIII concentrate has been shown to be an effective method of eliminating HTLV III/LAV from this product in laboratory studies.[21] The Medical and Scientific Advisory Council of the National Hemophilia Foundation has recently issued revised recommendations: (1) cryoprecipitate (because of the markedly fewer donors relative to Factor VIII concentrate) should be used in Factor VIII-deficient newborn infants and children younger than 4 years of age and in newly identified patients never treated with Factor VIII concentrates; (2) fresh frozen plasma should be used in Factor IX-deficient patients in the same categories; (3) desmopressin should be used whenever possible in patients with mild or moderate hemophilia A; and (4) "because heat-treated products appear to have no increase in untoward effects attributable to the heat treatment, treaters using coagulation factor concentrates should strongly consider changing to heat-treated products with the understanding that protection against AIDS is yet to be proven."[22]

HEPATITIS B VACCINE

Because this vaccine is made from pooled sera of persons who are at high risk for AIDS, many physicians have avoided the use of this vaccine for fear that it may be contaminated with the AIDS agent. Recent studies show that the inactivation process used in preparing the vaccine will inactivate the AIDS virus.[23] Other studies have shown that the vaccine contained no detectable AIDS virus-related nucleic acid sequences at a sensitivity of less than 1 pg of DNA per 20-μg dose of vaccine.[23] No seroconversions to the AIDS virus were detected in 19 individuals who had received vaccine.[23] To date 68 cases of AIDS have occurred in persons who were vaccinated; 65 of these cases occurred in persons with known risk factors for AIDS; the remaining 3 are under investigation.[23] This evidence should reassure physicians and those at high risk for hepatitis B that the vaccine is safe.

DAY CARE, SCHOOL AND FOSTER HOME ISSUES

Although there is no evidence that HTLV III/LAV is transmitted by casual person-to-person contact, the theoretical possibility of transmission in the school, day care and foster home setting creates difficult social problems for infected children. Conversely these settings may increase the immunocompromised child's exposure to infectious agents.

Physicians and health departments confronted with these problems have often chosen to place children in foster homes without other children younger than 6 years of age. Day care attendance is generally not recommended for AIDS children, because the oral behavior and incontinence of toddlers would be expected to increase the risk of transmission of infectious diseases. Some states have recommended that AIDS children be allowed to attend school if the child is continent, has no open or oozing lesions and behaves acceptably (e.g. does not bite) and if certain precautions can be taken

PRECAUTIONS

General. Precautions include: (1) using a bleach solution (10:1 ratio of water to bleach) to clean all spills of blood or other body fluids; (2) wearing gloves while cleaning these spills and treating any open lesions, and (3) placing any blood or body fluid-soaked items in a leak-proof bag for washing or disposal. The child's physician should consider removing the immunocompromised child from school during epidemics of infection such as measles or chickenpox.

Health care personnel. In addition to the above general precautions, health care personnel and others caring for AIDS patients should avoid accidental wounds from sharp instruments contaminated with potentially infectious material. Based on reports to the CDC, most accidental needlesticks occurred while recapping needles. This practice should be avoided Other detailed recommendations for health care personnel have been published by the CDC.[24]

Health care personnel can be reassured by evidence suggesting that the risk of transmission from AIDS patients is very small. A recent study found that none of 52 hospital personnel with documented accidental blood or mucous membrane exposure to infectious material from an AIDS patient developed AIDS or signs and symptoms associated with AIDS. Thirty-three of these persons were seronegative for HTLV III/LAV when tested for a mean of 8 months (range, 0.5 to 20 months) after the accident.[25] Of the 232 cases of AIDS in health care workers reported to the CDC, all but 23 belonged to known risk groups, and epidemiologic investigation of these 23 failed to document AIDS transmission through occupational exposure to a patient suspected of having HTLV III/LAV infection. Only one case of HTLV III/LAV infection in a hospital employee without other risks for AIDS and with documented parenteral exposure to an AIDS case has been reported.[26] The employee, a nurse, developed an acute illness about 2 weeks following a needlestick injury involving an AIDS case. The acute illness, characterized by fever, flulike symptoms, macular rash, arthralgias and generalized lymphadenopathy, resolved without specific therapy. A serum sample collected 27 days after the injury did not contain antibody to HTLV III/LAV. A second and third sample, collected at 49 and 57 days, contained antibody. The nurse remains asymptomatic 3 months after the injury.

HEALTH BURDEN

The health care needs of children with AIDS are enormous. The average daily cost of hospitalization for an AIDS patient has been estimated at $500 to $1000 per day Children with AIDS are hospitalized frequently for life-threatening illnesses which often require admission to the intensive care unit for costly therapy for respiratory failure and septic shock Those who are able to leave the hospital require frequent outpatient follow-up.

PSYCHOSOCIAL PROBLEMS

The populations of children at high risk for AIDS virus infection have many social problems in addition to the ones associated with AIDS. Children of women who are intravenous drug abusers are at high risk for premature delivery, opiate addition, neglect and abandonment Haitian families may be only recent arrivals to the United States and may have less access to medical care. Haitian parents and parents who abuse drugs may themselves be seriously ill or die from AIDS, leaving their children without care Children with hemophilia can have physical disabilities and emotional problems related to their disease Teenagers who acquire AIDS through homosexual contact are faced with having to admit their homosexuality to family and friends. Teenage drug abusers with AIDS must also cope with their intravenous drug addiction.

THE FUTURE

The recent discovery of the etiologic agent of AIDS greatly improves the ability to study this disease. The clinical spectrum of infection with HTLV III/LAV is being defined. Studies are currently under way to determine the transmission of HTLV III/LAV within families and among young children. Data from these studies should allow for better decisions regarding the need for isolation of the child with AIDS. Pregnancy outcome studies are needed to assess the risk of infection and disease in infants. Further studies to assure the safety of blood and blood products, to develop treatment strategies and to assess the long term prognosis of children with AIDS are needed. Surveillance for cases among health care workers and studies to assess the risk of infection in these persons should continue.

SUMMARY

A high level of suspicion by every provider is very important to ensure diagnosis and complete reporting Such active surveillance will enable effective national monitoring of the occurrence of the disease, the definition of new risk groups and the identification of unusual cases for further study. Physicians and health care workers should report all children and adults suspected of having AIDS to their state health departments who, in turn, report to the CDC.

It is clear that the number of cases of AIDS in children and adolescents is increasing because of either increased occurrence, increased diagnosis and/or increased surveillance. Pediatric health care personnel, especially those in high prevalence areas and those caring for high risk populations, need to be aware of AIDS and the problem encountered in caring for these children.

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Current Trends

Summary: Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus in the Workplace

The information and recommendations contained in this document have been developed with particular emphasis on health-care workers and others in related occupations in which exposure might occur to blood from persons infected with HTLV-III/LAV, the "AIDS virus." Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personal services and those preparing and serving food and beverages, this document also addresses personal-service and food-service workers. Finally, it addresses "other workers"—persons in settings, such as offices, schools, factories, and construction sites, where there is no known risk of AIDS virus transmission.

Because AIDS is a bloodborne, sexually transmitted disease that is not spread by casual contact, this document does *not* recommend routine HTLV-III/LAV antibody screening for the groups addressed. Because AIDS is not transmitted through preparation or serving of food and beverages, these recommendations state that food-service workers known to be infected with AIDS should not be restricted from work unless they have another infection or illness for which such restriction would be warranted.

This document contains detailed recommendations for precautions appropriate to prevent transmission of all bloodborne infectious diseases to people exposed—in the course of their duties—to blood from persons who may be infected with HTLV-III/LAV. They emphasize that health-care workers should take all possible precautions to prevent needlestick injury. The recommendations are based on the well-documented modes of HTLV-III/LAV transmission and incorporate a "worst case" scenario, the hepatitis B model of transmission. Because the hepatitis B virus is also bloodborne and is both hardier and more infectious than HTLV-III/LAV, recommendations that would prevent transmission of hepatitis B will also prevent transmission of AIDS.

Formulation of specific recommendations for health-care workers who perform invasive procedures is in progress.

Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/ Lymphadenopathy-Associated Virus in the Workplace

Persons at increased risk of acquiring infection with human T-lymphotropic virus type III/lymphadenopathy-associated virus (HTLV-III/LAV), the virus that causes acquired immunodeficiency syndrome (AIDS), include homosexual and bisexual men, intravenous (IV) drug abusers, persons transfused with contaminated blood or blood products, heterosexual contacts of persons with HTLV-III/LAV infection, and children born to infected mothers. HTLV-III/LAV is transmitted through sexual contact, parenteral exposure to infected blood or blood components, and perinatal transmission from mother to neonate. HTLV-III/LAV has been isolated from blood, semen, saliva, tears, breast milk, and urine and is likely to be isolated from some other body fluids, secretions, and excretions, but epidemiologic evidence has implicated only blood and semen in transmission. Studies of nonsexual household contacts of AIDS patients indicate that casual contact with saliva and tears does not result in transmission of infection. Spread of infection to household contacts of infected persons has not been detected when the household contacts have not been sex partners or have not been infants of infected mothers. The kind of nonsexual person-to-person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of HTLV-III/LAV.

As in the development of any such recommendations, the paramount consideration is the protection of the public's health. The following recommendations have been developed for all workers, particularly workers in occupations in which exposure might occur to blood from individuals infected with HTLV-III/LAV. These recommendations reinforce and supplement the specific recommendations that were published earlier for clinical and laboratory staffs (*1*) and for dental-care personnel and persons performing necropsies and morticians' services (*2*). Because of public concern about the purported risk of transmission of HTLV-III/LAV by persons providing personal services and by food and beverages, these recommendations contain information and recommendations for personal-service and food-service workers. Finally, these recommendations address workplaces in general where there is no known risk of transmission of HTLV-III/LAV (e.g., offices, schools, factories, construction sites). Formulation of specific recommendations for health-care workers (HCWs) who perform invasive procedures (e.g., surgeons, dentists) is in progress. Separate recommendations are also being developed to prevent HTLV-III/LAV transmission in prisons, other correctional facilities, and institutions housing individuals who may exhibit uncontrollable behavior (e.g., custodial institutions) and in the perinatal setting. In addition, separate recommendations have already been developed for children in schools and day-care centers (*3*).

HTLV-III/LAV-infected individuals include those with AIDS (*4*), those diagnosed by their physician(s) as having other illnesses due to infection with HTLV-III/LAV, and those who have virologic or serologic evidence of infection with HTLV-III/LAV but who are not ill.

These recommendations are based on the well-documented modes of HTLV-III/LAV transmission identified in epidemiologic studies and on comparison with the hepatitis B experience. Other recommendations are based on the hepatitis B model of transmission.

COMPARISON WITH THE HEPATITIS B VIRUS EXPERIENCE

The epidemiology of HTLV-III/LAV infection is similar to that of hepatitis B virus (HBV) infection, and much that has been learned over the last 15 years related to the risk of acquiring hepatitis B in the workplace can be applied to understanding the risk of HTLV-III/LAV transmission in the health-care and other occupational settings. Both viruses are transmitted through sexual contact, parenteral exposure to contaminated blood or blood products, and perinatal transmission from infected mothers to their offspring. Thus, some of the same major groups at high risk for HBV infection (e.g., homosexual men, IV drug abusers, persons with hemophilia, infants born to infected mothers) are also the groups at highest risk for HTLV-III/LAV infection. Neither HBV nor HTLV-III/LAV has been shown to be transmitted by casual contact in the workplace, contaminated food or water, or airborne or fecal-oral routes (*5*).

HBV infection is an occupational risk for HCWs, but this risk is related to degree of contact with blood or contaminated needles. HCWs who do not have contact with blood or needles contaminated with blood are not at risk for acquiring HBV infection in the workplace (*6-8*).

In the health-care setting, HBV transmission has not been documented between hospitalized patients, except in hemodialysis units, where blood contamination of the environment has been extensive or where HBV-positive blood from one patient has been transferred to another patient through contamination of instruments. Evidence of HBV transmission from HCWs to patients has been rare and limited to situations in which the HCWs exhibited high concentrations of virus in their blood (at least 100,000,000 infectious virus particles per ml of serum), and the HCWs sustained a puncture wound while performing traumatic procedures on patients or had exudative or weeping lesions that allowed virus to contaminate instruments or open wounds of patients (*9-11*).

Current evidence indicates that, despite epidemiologic similarities of HBV and HTLV-III/LAV infection, the risk for HBV transmission in health-care settings far exceeds that for HTLV-III/LAV transmission. The risk of acquiring HBV infection following a needlestick from an HBV carrier ranges from 6% to 30% (*12,13*), far in excess of the risk of HTLV-III/LAV infection following a needlestick involving a source patient infected with HTLV-III/LAV, which is less than 1%. In addition, all HCWs who have been shown to transmit HBV infection in health-care settings have belonged to the subset of chronic HBV carriers who, when tested, have exhibited evidence of exceptionally high concentrations of virus (at least 100,000,000 infectious virus particles per ml) in their blood. Chronic carriers who have substantially lower concentrations of virus in their blood have not been implicated in transmission in the health-care setting (*9-11,14*). The HBV model thus represents a "worst case" condition in regard to transmission in health-care and other related settings. Therefore, recommendations for the control of HBV infection should, if followed, also effectively prevent spread of HTLV-III/LAV. Whether additional measures are indicated for those HCWs who perform invasive procedures will be addressed in the recommendations currently being developed.

Routine screening of all patients or HCWs for evidence of HBV infection has never been recommended. Control of HBV transmission in the health-care setting has emphasized the implementation of recommendations for the appropriate handling of blood, other body fluids, and items soiled with blood or other body fluids.

TRANSMISSION FROM PATIENTS TO HEALTH-CARE WORKERS

HCWs include but are not limited to nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, phlebotomists, dialysis personnel, paramedics, emergency medical technicians, medical examiners, morticians, housekeepers, laundry workers, and others whose work involves contact with patients, their blood or other body fluids, or corpses.

Recommendations for HCWs emphasize precautions appropriate for preventing transmission of bloodborne infectious diseases, including HTLV-III/LAV and HBV infections. Thus, these precautions should be enforced routinely, as should other standard infection-control precautions, regardless of whether HCWs or patients are known to be infected with HTLV-III/LAV or HBV. In addition to being informed of these precautions, all HCWs, including students and housestaff, should be educated regarding the epidemiology, modes of transmission, and prevention of HTLV-III/LAV infection.

Risk of HCWs acquiring HTLV-III/LAV in the workplace. Using the HBV model, the highest risk for transmission of HTLV-III/LAV in the workplace would involve parenteral exposure to a needle or other sharp instrument contaminated with blood of an infected patient. The risk to HCWs of acquiring HTLV-III/LAV infection in the workplace has been evaluated in several studies. In five separate studies, a total of 1,498 HCWs have been tested for antibody to HTLV-III/LAV. In these studies, 666 (44.5%) of the HCWs had direct parenteral (needlestick or cut) or mucous membrane exposure to patients with AIDS or HTLV-III/LAV infection. Most of these exposures were to blood rather than to other body fluids. None of the HCWs whose initial serologic tests were negative developed subsequent evidence of HTLV-III/LAV infection following their exposures. Twenty-six HCWs in these five studies were seropositive when first tested; all but three of these persons belonged to groups recognized to be at increased risk for AIDS (*15*). Since one was tested anonymously, epidemiologic information was available on only two of these three seropositive HCWs. Although these two HCWs were reported as probable occupationally related HTLV-III/LAV infection (*15,16*), neither had a preexposure nor an early postexposure serum sample available to help determine the onset of infection. One case reported from England describes a nurse who seroconverted following an accidental parenteral exposure to a needle contaminated with blood from an AIDS patient (*17*).

In spite of the extremely low risk of transmission of HTLV-III/LAV infection, even when needlestick injuries occur, more emphasis must be given to precautions targeted to prevent needlestick injuries in HCWs caring for any patient, since such injuries continue to occur even during the care of patients who are known to be infected with HTLV-III/LAV.

Precautions to prevent acquisition of HTLV-III/LAV infection by HCWs in the workplace. These precautions represent prudent practices that apply to preventing transmission of HTLV-III/LAV and other bloodborne infections and should be used routinely (*18*).

1. Sharp items (needles, scalpel blades, and other sharp instruments) should be considered as potentially infective and be handled with extraordinary care to prevent accidental injuries.
2. Disposable syringes and needles, scalpel blades, and other sharp items should be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
3. When the possibility of exposure to blood or other body fluids exists, routinely recommended precautions should be followed. The anticipated exposure may require gloves alone, as in handling items soiled with blood or equipment contaminated with blood or other body fluids, or may also require gowns, masks, and eye-coverings when performing procedures involving more extensive contact with blood or potentially infective body fluids, as in some dental or endoscopic procedures or postmortem examinations. Hands should be washed thoroughly and immediately if they accidentally become contaminated with blood.
4. To minimize the need for emergency mouth-to-mouth resuscitation, mouth pieces, resuscitation bags, or other ventilation devices should be strategically located and available for use in areas where the need for resuscitation is predictable.
5. Pregnant HCWs are not known to be at greater risk of contracting HTLV-III/LAV infections than HCWs who are not pregnant; however, if a HCW develops HTLV-III/LAV infection during pregnancy, the infant is at increased risk of infection resulting from perinatal transmission. Because of this risk, pregnant HCWs should be especially familiar with precautions for the preventing HTLV-III/LAV transmission (*19*).

Precautions for HCWs during home care of persons infected with HTLV-III/LAV Persons infected with HTLV-III/LAV can be safely cared for in home environments. Studies of family members of patients infected with HTLV-III/LAV have found no evidence of HTLV-III/LAV transmission to adults who were not sexual contacts of the infected patients or to children who were not at risk for perinatal transmission (*3*). HCWs providing home care face the same risk of transmission of infection as HCWs in hospitals and other health-care settings, especially if there are needlesticks or other parenteral or mucous membrane exposures to blood or other body fluids.

When providing health-care service in the home to persons infected with HTLV-III/LAV, measures similar to those used in hospitals are appropriate. As in the hospital, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand. Needles and other sharp items should be placed into puncture-resistant containers and disposed of in accordance with local regulations for solid waste. Blood and other body fluids can be flushed down the toilet. Other items for disposal that are contaminated with blood or other body fluids that cannot be flushed down the toilet should be wrapped securely in a plastic bag that is impervious and sturdy (not easily penetrated). It should be placed in a second bag before being discarded in a manner consistent with local regulations for solid waste disposal. Spills of blood or other body fluids should be cleaned with soap and water or a household detergent. As in the hospital, individuals cleaning up such spills should wear disposable gloves. A disinfectant solution or a freshly prepared solution of sodium hypochlorite (household bleach, see below) should be used to wipe the area after cleaning.

Precautions for providers of prehospital emergency health care Providers of prehospital emergency health care include the following: paramedics, emergency medical technicians, law enforcement personnel, firefighters, lifeguards, and others whose job might require them to provide first-response medical care. The risk of transmission of infection, including HTLV-III/LAV infection, from infected persons to providers of prehospital emergency health care should be no higher than that for HCWs providing emergency care in the hospital if appropriate precautions are taken to prevent exposure to blood or other body fluids.

Providers of prehospital emergency health care should follow the precautions outlined above for other HCWs. No transmission of HBV infection during mouth-to-mouth resuscitation has been documented. However, because of the theoretical risk of salivary transmission of HTLV-III/LAV during mouth-to-mouth resuscitation, special attention should be given to the use of disposable airway equipment or resuscitation bags and the wearing of gloves when in contact with blood or other body fluids. Resuscitation equipment and devices known or suspected to be contaminated with blood or other body fluids should be used once and disposed of or be thoroughly cleaned and disinfected after each use.

Management of parenteral and mucous membrane exposures of HCWs If a HCW has a parenteral (e.g., needlestick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III/LAV infection. If the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III/LAV infection. If the source patient has AIDS or other evidence of HTLV-III/LAV infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV infection as soon as possible after the exposure, and, if seronegative, retested after 6 weeks and on a periodic basis thereafter (e.g., 3, 6, and 12 months following exposure) to determine if transmission has occurred. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCWs should receive counseling about the risk of infection and follow U.S. Public Health Service (PHS) recommendations for preventing transmission of AIDS (*20,21*). If the source patient is seronegative and has no other evidence of HTLV-III/LAV infection, no further follow-up of the HCW is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the source patient was infected.

Serologic testing of patients Routine serologic testing of all patients for antibody to HTLV-III/LAV is not recommended to prevent transmission of HTLV-III/LAV infection in the workplace. Results of such testing are unlikely to further reduce the risk of transmission, which, even with documented needlesticks, is already extremely low. Furthermore, the risk of needlestick and other parenteral exposures could be reduced by emphasizing and more consistently implementing routinely recommended infection-control precautions (e.g., not recapping needles). Moreover, results of routine serologic testing would not be available for emergency cases and patients with short lengths of stay and additional tests to determine whether a positive test was a true or false positive would be required in populations with a low prevalence of infection However this recommendation is based only on considerations of occupational risks and should not be construed as a recommendation against other uses of the serologic test, such as for diagnosis or to facilitate medical management of patients Since the experience with infected patients varies substantially among hospitals (75% of all AIDS cases have been reported by only 280 of the more than 6,000 acute-care hospitals in the United States), some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients

TRANSMISSION FROM HEALTH-CARE WORKERS TO PATIENTS

Risk of transmission of HTLV-III/LAV infection from HCWs to patients Although there is no evidence that HCWs infected with HTLV-III/LAV have transmitted infection to patients a risk of transmission of HTLV-III/LAV infection from HCWs to patients would exist in situations where there is both (1) a high degree of trauma to the patient that would provide a portal of entry for the virus (e g , during invasive procedures) and (2) access of blood or serous fluid from the infected HCW to the open tissue of a patient, as could occur if the HCW sustains a needlestick or scalpel injury during an invasive procedure HCWs known to be infected with HTLV-III/LAV who do not perform invasive procedures need not be restricted from work unless they have evidence of other infection or illness for which any HCW should be restricted Whether additional restrictions are indicated for HCWs who perform invasive procedures is currently being considered.

Precautions to prevent transmission of HTLV-III/LAV infection from HCWs to patients These precautions apply to all HCWs, regardless of whether they perform invasive procedures (1) All HCWs should wear gloves for direct contact with mucous membranes or nonintact skin of all patients and (2) HCWs who have exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves

Management of parenteral and mucous membrane exposures of patients If a patient has a parenteral or mucous membrane exposure to blood or other body fluids of a HCW, the patient should be informed of the incident and the same procedure outlined above for exposures of HCWs to patients should be followed for both the source HCW and the potentially exposed patient. Management of this type of exposure will be addressed in more detail in the recommendations for HCWs who perform invasive procedures

Serologic testing of HCWs. Routine serologic testing of HCWs who do not perform invasive procedures (including providers of home and prehospital emergency care) is not recommended to prevent transmission of HTLV-III/LAV infection. The risk of transmission is extremely low and can be further minimized when routinely recommended infection-control precautions are followed However, serologic testing should be available to HCWs who may wish to know their HTLV-III/LAV infection status Whether indications exist for serologic testing of HCWs who perform invasive procedures is currently being considered

Risk of occupational acquisition of other infectious diseases by HCWs infected with HTLV-III/LAV HCWs who are known to be infected with HTLV-III/LAV and who have defective immune systems are at increased risk of acquiring or experiencing serious complications of other infectious diseases Of particular concern is the risk of severe infection following exposure to patients with infectious diseases that are easily transmitted if appropriate precautions are not taken (e g., tuberculosis) HCWs infected with HTLV-III/LAV should be counseled about the potential risk associated with taking care of patients with transmissible infections and should continue to follow existing recommendations for infection control to minimize their risk of exposure to other infectious agents (*18,19*). The HCWs' personal physician(s), in conjunction with their institutions' personnel health services or medical directors, should determine on an individual basis whether the infected HCWs can adequately and safely perform patient-care duties and suggest changes in work assignments if indicated In making this determination, recommendations of the Immunization Practices Advisory Committee and institutional policies concerning requirements for vaccinating HCWs with live-virus vaccines should also be considered

STERILIZATION, DISINFECTION, HOUSEKEEPING, AND WASTE DISPOSAL TO PREVENT TRANSMISSION OF HTLV-III/LAV

Sterilization and disinfection procedures currently recommended for use (*22,23*) in health care and dental facilities are adequate to sterilize or disinfect instruments devices or othe items contaminated with the blood or other body fluids from individuals infected with HTLV-II LAV Instruments or other nondisposable items that enter normally sterile tissue or the vascul system or through which blood flows should be sterilized before reuse Surgical instrumen used on all patients should be decontaminated after use rather than just rinsed with water. Decontamination can be accomplished by machine or by hand cleaning by trained personnel wearing appropriate protective attire (*24*) and using appropriate chemical germicides. Instruments or other nondisposable items that touch intact mucous membranes should receive high-level disinfection.

Several liquid chemical germicides commonly used in laboratories and health-care facilities have been shown to kill HTLV-III/LAV at concentrations much lower than are used in practice (*25*). When decontaminating instruments or medical devices, chemical germicides that are registered with and approved by the U.S. Environmental Protection Agency (EPA) as "sterilants" can be used either for sterilization or for high-level disinfection depending on contact time; germicides that are approved for use as "hospital disinfectants" and are mycobactericidal when used at appropriate dilutions can also be used for high-level disinfection of devices and instruments. Germicides that are mycobactericidal are preferred because mycobacteria represent one of the most resistant groups of microorganisms; therefore, germicides that are effective against mycobacteria are also effective against other bacterial and viral pathogens. When chemical germicides are used, instruments or devices to be sterilized or disinfected should be thoroughly cleaned before exposure to the germicide, and the manufacturer's instructions for use of the germicide should be followed.

Laundry and dishwashing cycles commonly used in hospitals are adequate to decontaminate linens, dishes, glassware, and utensils. When cleaning environmental surfaces, housekeeping procedures commonly used in hospitals are adequate; surfaces exposed to blood and body fluids should be cleaned with a detergent followed by decontamination using an EPA-approved hospital disinfectant that is mycobactericidal. Individuals cleaning up such spills should wear disposable gloves. Information on specific label claims of commercial germicides can be obtained by writing to the Disinfectants Branch, Office of Pesticides, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C., 20460.

In addition to hospital disinfectants, a freshly prepared solution of sodium hypochlorite (household bleach) is an inexpensive and very effective germicide (*25*). Concentrations ranging from 5,000 ppm (a 1:10 dilution of household bleach) to 500 ppm (a 1:100 dilution) sodium hypochlorite are effective, depending on the amount of organic material (e.g., blood, mucus, etc.) present on the surface to be cleaned and disinfected.

Sharp items should be considered as potentially infective and should be handled and disposed of with extraordinary care to prevent accidental injuries. Other potentially infective waste should be contained and transported in clearly identified impervious plastic bags. If the outside of the bag is contaminated with blood or other body fluids, a second outer bag should be used. Recommended practices for disposal of infective waste (*23*) are adequate for disposal of waste contaminated by HTLV-III/LAV. Blood and other body fluids may be carefully poured down a drain connected to a sanitary sewer.

CONSIDERATIONS RELEVANT TO OTHER WORKERS

Personal-service workers (PSWs). PSWs are defined as individuals whose occupations involve close personal contact with clients (e.g., hairdressers, barbers, estheticians, cosmetologists, manicurists, pedicurists, massage therapists). PSWs whose services (tattooing, ear piercing, acupuncture, etc.) require needles or other instruments that penetrate the skin should follow precautions indicated for HCWs. Although there is no evidence of transmission of HTLV-III/LAV from clients to PSWs, from PSWs to clients, or between clients of PSWs, a risk of transmission would exist from PSWs to clients and vice versa in situations where there is both (1) trauma to one of the individuals that would provide a portal of entry for the virus and (2) access of blood or serous fluid from one infected person to the open tissue of the other, as could occur if either sustained a cut. A risk of transmission from client to client exists when instruments contaminated with blood are not sterilized or disinfected between clients. However, HBV transmission has been documented only rarely in acupuncture, ear piercing, and tattoo establishments and never in other personal-service settings, indicating that any risk for HTLV-III/LAV transmission in personal-service settings must be extremely low.

All PSWs should be educated about transmission of bloodborne infections, including HTLV-III/LAV and HBV. Such education should emphasize principles of good hygiene, antisepsis, and disinfection. This education can be accomplished by national or state professional organizations, with assistance from state and local health departments, using lectures at meetings or self-instructional materials. Licensure requirements should include evidence of such education. Instruments that are intended to penetrate the skin (e.g., tattooing and acupuncture needles, ear piercing devices) should be used once and disposed of or be thoroughly cleaned and sterilized after each use using procedures recommended for use in health-care institutions. Instruments not intended to penetrate the skin but which may become contaminated with blood (e.g., razors) should be used for only one client and be disposed of or thoroughly cleaned and disinfected after use using procedures recommended for use in health-care institutions. Any PSW with exudative lesions or weeping dermatitis, regardless of HTLV-III/LAV infection status, should refrain from direct contact with clients until the condition resolves. PSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infections or illnesses for which any PSW should also be restricted.

Routine serologic testing of PSWs for antibody to HTLV-III/LAV is not recommended to prevent transmission from PSWs to clients.

Food-service workers (FSWs). FSWs are defined as individuals whose occupations involve the preparation or serving of food or beverages (e.g., cooks, caterers, servers, waiters, bartenders, airline attendants). All epidemiologic and laboratory evidence indicates that bloodborne and sexually transmitted infections are not transmitted during the preparation or serving of food or beverages, and no instances of HBV or HTLV-III/LAV transmission have been documented in this setting.

All FSWs should follow recommended standards and practices of good personal hygiene and food sanitation (*26*). All FSWs should exercise care to avoid injury to hands when preparing food. Should such an injury occur, both aesthetic and sanitary considerations would dictate that food contaminated with blood be discarded. FSWs known to be infected with HTLV-III/LAV need not be restricted from work unless they have evidence of other infection or illness for which any FSW should also be restricted.

Routine serologic testing of FSWs for antibody to HTLV-III/LAV is not recommended to prevent disease transmission from FSWs to consumers.

Other workers sharing the same work environment. No known risk of transmission to co-workers, clients, or consumers exists from HTLV-III/LAV-infected workers in other settings (e.g., offices, schools, factories, construction sites). This infection is spread by sexual contact with infected persons, injection of contaminated blood or blood products, and by perinatal transmission. Workers known to be infected with HTLV-III/LAV should not be restricted from work solely based on this finding. Moreover, they should not be restricted from using telephones, office equipment, toilets, showers, eating facilities, and water fountains. Equipment contaminated with blood or other body fluids of any worker, regardless of HTLV-III/LAV infection status, should be cleaned with soap and water or a detergent. A disinfectant solution or a fresh solution of sodium hypochlorite (household bleach, see above) should be used to wipe the area after cleaning.

OTHER ISSUES IN THE WORKPLACE

The information and recommendations contained in this document do not address all the potential issues that may have to be considered when making specific employment decisions for persons with HTLV-III/LAV infection. The diagnosis of HTLV-III/LAV infection may evoke unwarranted fear and suspicion in some co-workers. Other issues that may be considered include the need for confidentiality, applicable federal, state, or local laws governing occupational safety and health, civil rights of employees, workers' compensation laws, provisions of collective bargaining agreements, confidentiality of medical records, informed consent, employee and patient privacy rights, and employee right-to-know statutes.

DEVELOPMENT OF THESE RECOMMENDATIONS

The information and recommendations contained in these recommendations were developed and compiled by CDC and other PHS agencies in consultation with individuals representing various organizations. The following organizations were represented: Association of State and Territorial Health Officials, Conference of State and Territorial Epidemiologists, Association of State and Territorial Public Health Laboratory Directors, National Association of County Health Officials, American Hospital Association, United States Conference of Local Health Officers, Association for Practitioners in Infection Control, Society of Hospital Epidemiologists of America, American Dental Association, American Medical Association, American Nurses' Association, American Association of Medical Colleges, American Association of Dental Schools, National Institutes of Health, Food and Drug Administration, Food Research Institute, National Restaurant Association, National Hairdressers and Cosmetologists Association, National Gay Task Force, National Funeral Directors and Morticians Association, American Association of Physicians for Human Rights, and National Association of Emergency Medical Technicians. The consultants also included a labor union representative, an attorney, a corporate medical director, and a pathologist. However, these recommendations may not reflect the views of individual consultants or the organizations they represented.

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Update: Human Immunodeficiency Virus Infections in Health-Care Workers Exposed to Blood of Infected Patients

Six persons who provided health care to patients with human immunodeficiency virus (HIV) infection and who denied other risk factors have previously been reported to have HIV infection. Four of these cases followed needle-stick exposures to blood from patients infected with HIV (*1-4*). The two additional cases involved persons who provided nursing care to persons with HIV infection. Although neither of these two persons sustained needle-stick injuries, both had extensive contact with blood or body fluids of the infected patient, and neither observed routinely recommended barrier precautions (*5,6*).

CDC has received reports of HIV infection in three additional health-care workers following non-needle-stick exposures to blood from infected patients. The exposures occurred during 1986 in three different geographic areas. Although these three cases represent rare events, they reemphasize the need for health-care workers to adhere rigorously to existing infection control recommendations for minimizing the risk of exposure to blood and body fluids of all patients (*7-9*).

Health-Care Worker 1: A female health-care worker assisting with an unsuccessful attempt to insert an arterial catheter in a patient suffering a cardiac arrest in an emergency room applied pressure to the insertion site to stop the bleeding. During the procedure, she may have had a small amount of blood on her index finger for about 20 minutes before washing her hands. Afterwards, she may also have assisted in cleaning the room but did not recall any other exposures to the patient's blood or body fluids. She had no open wounds, but her hands were chapped. Although she often wore gloves when anticipating exposure to blood, she was not wearing gloves during this incident.

The patient with the cardiac arrest died. A postmortem examination identified *Pneumocystis carinii* pneumonia, and a blood sample was positive for HIV antibody by enzyme immunoassay (EIA) and Western blot methods. Twenty days after the incident, the health-care worker became ill with fever, myalgia, extreme fatigue, sore throat, nausea, vomiting, diarrhea, a 14-pound weight loss, and generalized lymphadenopathy which her physician diagnosed as a viral syndrome. That illness lasted 3 weeks. She felt much better 9 weeks after the incident, and, when she was examined 6 months after the incident, all signs and symptoms had resolved. She had donated blood 8 months before the incident and was negative for HIV antibody by EIA. She donated again 16 weeks after the incident and was positive for HIV by EIA and Western blot (bands p24 and gp41). Serum samples obtained 20 and 23 weeks after the incident were also positive for HIV antibody. She stated that for over 8 years her only sexual partner had been her husband, who denied risk factors for HIV and was seronegative for HIV antibody. She denied ever receiving a blood transfusion, ever using intravenous drugs, or having any needle sticks or other significant exposures to blood or body fluids in the past 8 years. Her serologic test for syphilis was negative. Fifteen other employees who assisted in the care of the patient were seronegative at least 4 months after the exposure.

Health-Care Worker 2: A female phlebotomist was filling a 10 ml vacuum blood collection tube with blood from an outpatient with a suspected HIV infection when the top of the tube flew off and blood splattered around the room, on her face, and in her mouth. She was wearing gloves to protect her hands and was wearing eyeglasses so she did not think she got any blood in her eyes. She had facial acne but no open wounds. She washed the blood off immediately after the exposure. The outpatient's blood sample was positive for HIV antibody by EIA and Western blot, and a hepatitis B surface antigen test was negative. The phlebotomist's EIA was negative the day after the incident and again 8 weeks later. When she donated blood 9 months after the exposure, she was positive for HIV antibody by EIA and Western blot (bands p24 and gp41). She has had no symptoms. She denied having any sexual contact during the previous 2 years, ever using drugs intravenously, or ever receiving a transfusion.

Two months after the incident, she scratched the back of her hand with a needle used to draw blood from en intravenous drug abuser of unknown HIV-antibody status. She did not bleed as a result of the scratch and has not had any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative. A coworker who was splattered with blood on the face and in the mouth during the same incident remains seronegative 1 year after the incident.

Health-Care Worker 3: A female medical technologist was manipulating an apheresis machine (a device to separate blood components) to correct a problem that developed during an outpatient procedure when blood spilled, covering most of her hands and forearms She was not wearing gloves She does not recall having any open wounds on her hands or any mucous-membrane exposure However, she had dermatitis on one ear and may have touched it. She washed the blood off herself and the machine several minutes after the spill. The patient undergoing the apheresis had denied risk factors for HIV infection. However, a blood sample from the patient was positive for HIV antibody by EIA and Western blot methods and negative for hepatitis B surface antigen the next day. The technologist's HIV-antibody tests were negative 5 days after the exposure and again 6 weeks later. Eight weeks after the exposure, she had an influenza-like illness with fever, myalgia, diarrhea, hives, and a pruritic red macular rash on her arms and legs. The illness resolved after a few weeks, and her physician thought the illness was probably a viral syndrome. Three months after the incident, she was positive for HIV antibody by EIA and Western blot methods (band p24 alone). Four months after the incident, a Western blot was positive (bands p24 and gp41). She indicated that for more than 8 years her only sexual partner had been her husband, who denied risk factors for HIV infection and was seronegative for HIV antibody She denied ever receiving a transfusion, ever using intravenous drugs, or having any needle-stick injuries in over 2 years. Her serologic tests for syphilis and hepatitis B were negative She has an immunologic disorder which had been treated with corticosteroids in the past, but she had not taken any immunosuppressive medication for the past year. A coworker with a similar exposure during the same procedure remains seronegative after 3 months.

***Reported by:** Hospital Infections Program and AIDS Program, Center for Infectious Diseases, CDC*

Editorial Note: Three instances of health-care workers with HIV infections associated with skin or mucous-membrane exposure to blood from HIV-infected patients are reported above. Careful investigation of these three cases did not identify other risk factors for HIV infection, although unrecognized or forgotten needle-stick exposures to other infected patients cannot be totally excluded The exact route of transmission in these three cases is not known Health-Care Worker 1 had chapped hands, and the duration of contact with the blood of the patient experiencing a cardiac arrest may have been as long as 20 minutes Health-Care Worker 2 sustained contamination of oral mucous membranes This individual also had acne but did not recall having open lesions In addition, she had sustained a scratch from a needle used to draw blood from an intravenous drug abuser of unknown HIV-infection status. Health-Care Worker 3 had a history of dermatitis involving an ear. Health-Care Workers 1 and 3 were not wearing gloves when direct contact with blood occurred. Health-Care Worker 2 was wearing gloves, but blood contaminated her face and mouth.

Three ongoing prospective studies provide data on the magnitude of the risk of HIV infection incurred when health-care workers are exposed to blood of infected patients through needle-stick wounds or contamination of an open wound or mucous membrane. In a CDC cooperative surveillance project (*10*), a total of 1,097 health-care workers with parenteral or mucous-membrane exposure to the blood of patients with AIDS or other manifestations of HIV infection had been enrolled as of March 31, 1987. Needle-stick injuries and cuts with sharp objects accounted for 969 (89%) of the exposures to blood; 298 of these had paired serum samples tested for HIV antibody One (0.3%) seroconverted (*2*), indicating that the risk of transmission during these exposures is very low. In addition, 70 health-care workers had open wounds exposed to blood, and 58 had mucous membrane exposed to blood. Postexposure serum samples from 82 of these 128 workers have been tested for antibody to HIV; none was seropositive.

In a study at the National Institutes of Health (*11*) through April 30, 1987, none of the 103 workers with percutaneous exposures and none of the 229 workers with mucous-membrane exposures to blood or body fluids of patients with AIDS was seropositive. At the University of California (*12*), none of 63 workers with open wounds or mucous membranes exposed to blood or body fluids of patients with AIDS was seropositive Although the precise risk of transmission during exposures of open wounds or mucous membranes to contaminated blood cannot be defined, these studies indicate that it must be very low.

The three cases reported here suggest that exposure of skin or mucous membranes to contaminated blood may rarely result in transmission of HIV The magnitude of the risk is not known since data on the frequency with which such exposures occur are not available. Skin and mucous-membrane exposures are thought to occur much more commonly than needle sticks, and the risk associated with skin or mucous-membrane exposures is likely to be far lower than that associated with needle-stick injuries Nonetheless, the increasing prevalence of HIV infection increases the potential for such exposures, especially when routinely recommended precautions are not followed

It is unlikely that routine serologic testing for HIV infection of all patients admitted to hospitals would have prevented these exposures since two of the three exposures occurred in the outpatient clinic setting, and one occurred during a resuscitation effort in an emergency room shortly after the arrival of the patient. At the time of exposure, Health-Care Worker 2 suspected that the source patient was infected with HIV, but Health-Care Workers 1 and 3 did not The hospital where Health-Care Worker 3 was exposed has a protocol for apheresis which normally involves HIV-antibody testing of donors, however, such testing was not done in advance of the procedure. Previous CDC recommendations have emphasized the value of HIV serologic testing for patient diagnosis and management and for prevention and control of HIV transmission (*13*) and have stated that some hospitals in certain geographic areas may deem it appropriate to initiate serologic testing of patients (*7*) Such testing may also provide an opportunity to reduce the risk of HIV infection to health-care workers, but it has not been established that knowledge of a patient's serologic status increases the compliance of health-care workers with recommended precautions

These cases emphasize again the need to implement and strictly enforce previously published recommendations for minimizing the risk of exposure to blood and body fluids of all patients in order to prevent transmission of HIV infection in the workplace and during invasive procedures (*7-9*).

1 As previously recommended, routine precautions must be followed when there is a possibility of exposure to blood or other body fluids The anticipated exposure may require gloves alone (e.g., when placing an intravascular catheter or handling items soiled with blood or equipment contaminated with blood or other body fluids). Procedures involving more extensive contact with blood or potentially infective body fluids (e.g., some dental or endoscopic procedures or postmortem examinations) may require gloves, gowns, masks, and eye-coverings Hands and other contaminated skin surfaces should be washed thoroughly and immediately if accidentally contaminated with blood (*7*). These precautions deserve particular emphasis in emergency care settings in which the risk of blood exposure is increased and the infectious status of the patient is usually unknown (*14*).

2 Previous recommendations have emphasized management of parenteral and mucous-membrane exposures of health-care workers*. In addition, health-care workers who are involved in incidents that result in cutaneous exposures involving large amounts of blood or prolonged contact with blood—especially when the exposed skin is chapped, abraded, or afflicted with dermatitis—should follow these same recommendations. Moreover, serologic testing should be available to all health-care workers who are concerned that they may have been infected with HIV.

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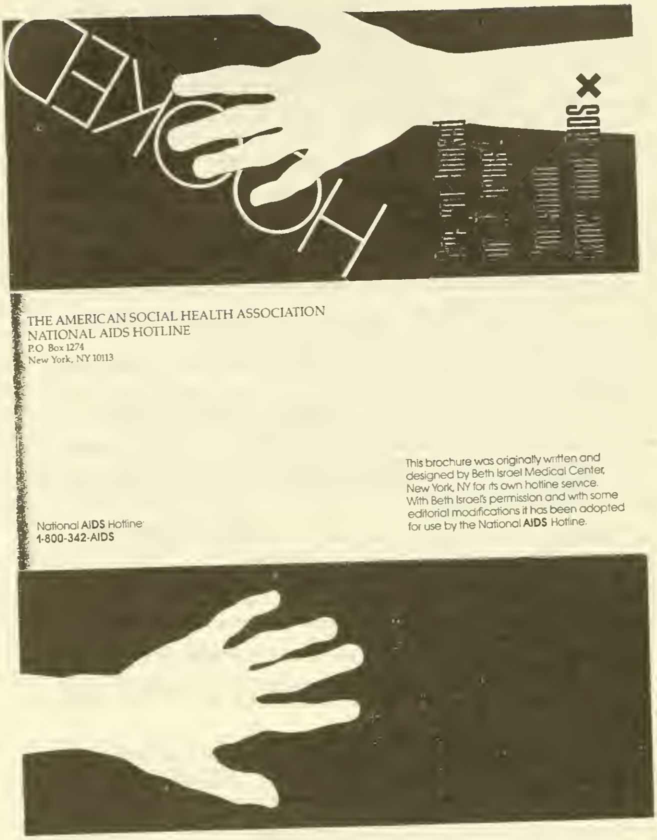
*If a HCW [health-care worker] has a parenteral (e.g., needlestick or cut) or mucous membrane (e.g., splash to the eye or mouth) exposure to blood or other body fluids, the source patient should be assessed clinically and epidemiologically to determine the likelihood of HTLV-III/LAV [sic] infection If the assessment suggests that infection may exist, the patient should be informed of the incident and requested to consent to serologic testing for evidence of HTLV-III/LAV [sic] infection If the source patient has AIDS or other evidence of HTLV-III/LAV [sic] infection, declines testing, or has a positive test, the HCW should be evaluated clinically and serologically for evidence of HTLV-III/LAV [sic] infection as soon as possible after the exposure, and, if seronegative, retested after 6 weeks and on a periodic basis thereafter (e.g., 3, 6, and 12 months following exposure) to determine if transmission has occurred During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed HCWs should receive counseling about the risk of infection and follow U.S Public Health Service (PHS) recommendations for preventing transmission of AIDS (*15,16*). If the source patient is seronegative and has no other evidence of HTLV-III/LAV [sic] infection, no further follow-up of the HCW is necessary If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the source patient was infected (*7*).



THE AMERICAN SOCIAL HEALTH ASSOCIATION
NATIONAL AIDS HOTLINE
P.O Box 1274
New York, NY 10113

National **AIDS** Hotline:
1-800-342-AIDS

This brochure was originally written and designed by Beth Israel Medical Center, New York, NY for its own hotline service. With Beth Israel's permission and with some editorial modifications it has been adopted for use by the National **AIDS** Hotline.

AIDS, or Acquired Immune Deficiency Syndrome, is a life-threatening disease that damages the body's ability to fight invading germs, viruses and other infections.

AIDS is not spread from person to person by casual contact. However, certain people are at greater risk of developing **AIDS** because of their lifestyles and habits.

YOU ARE AT RISK FOR AIDS IF YOU…

- have mainlined or skinpopped drugs
- have shared needles or works
- have frequented shooting galleries or rented works
- have had sex with someone who has been exposed to the **AIDS** virus.

YOU SHOULD SEEK HELP IF YOU HAVE…

- unexplained and prolonged fatigue
- swollen glands in your neck, armpits or groin, with or without pain
- whitish blotches or bumps inside your mouth (with a sore throat); these may also be found in the nose, eyelids or rectum
- rapid weight loss (more than 10 pounds) in the past two months
- unexplained fever, chills and drenching night sweats lasting more than several weeks
- persistent diarrhea or bloody stools
- a stubborn, dry cough not related to a cold, allergies or smoking
- persistent chest pain or shortness of breath
- trouble swallowing or severe heartburn that persists
- purple lesions or discoloration of skin.

If any of these symptoms appear, it **DOES NOT** mean you have **AIDS**. It **DOES** mean you should seek medical advice

HOW CAN YOU PROTECT YOURSELF FROM AIDS?

- **THE BEST PROTECTION IS TO STOP USING DRUGS. GET HELP TO OVERCOME YOUR ADDICTION.**
- **IF YOU DO USE DRUGS, DO NOT SHARE NEEDLES OR WORKS.** Learn how to clean your works.
- **DON'T RENT WORKS. DON'T GO TO SHOOTING GALLERIES.**
- **ALWAYS USE CONDOMS (RUBBERS) WHEN HAVING SEX.**

IF YOU ARE OR HAVE BEEN A DRUG USER, YOU MAY HAVE ALREADY BEEN EXPOSED TO THE AIDS VIRUS.

Remember, you can look and feel healthy, but still carry the **AIDS** virus. Even if you have *already been exposed* — there are two things you can do:

- Don't risk further exposure
- Don't spread the virus to others

It can take as long as five years after exposure to **AIDS** for any sign or symptom of the disease to appear. If you shoot drugs, or have done so, get a physical exam and seek help to get over your addiction.

What Women Should Know About AIDS

What Is AIDS?

AIDS stands for ***Acquired Immune Deficiency Syndrome***.

AIDS is caused by a virus known as HIV (human immunodeficiency virus). This virus harms the body's immune system so it cannot fight off infections and cancers.

There is no cure for AIDS. But it is the infection or cancer that kills the person, not the AIDS virus itself.

The number one cause of death of persons with AIDS is an infection in the lungs called *Pneumocystis carinii* pneumonia (PCP). Persons with AIDS can also get a cancer called Kaposi's sarcoma (KS). KS is a cancer of the tissues beneath the skin. It is possible for people with AIDS to get both PCP and KS.

How Do People Get AIDS?

AIDS is spread through the exchange of body fluids, mostly semen and blood. It is definitely spread through sexual contact or intercourse. AIDS is not spread by casual contact. It is not an airborne disease.

So far, in the United States, gay and bisexual men have been most at risk of getting AIDS. More than 70% of cases have been in these two groups.

Another group at high risk of getting AIDS is intravenous (IV) drug users who share needles. The virus is passed along when needles are not sterilized between uses. Blood holding the virus may be left on the needle and passed to the next user. Wiping off the needle doesn't get rid of the virus.

Some heterosexual (straight) men and women are now getting AIDS. A growing number of infants also have AIDS. Most of these babies had mothers who either had AIDS or were exposed to the virus.

A few people have gotten the virus from AIDS-contaminated blood transfusions. Blood is now tested for the AIDS virus so chances of getting infected this way are small.

Once a person has been exposed to the virus, it can take anywhere from 6 months to 6 years to develop AIDS. This is called the incubation period. It is not known how many people exposed to the virus will develop AIDS.

Some people exposed to the AIDS virus never actually get it themselves. These people are called "carriers." Although carriers look healthy, they can give AIDS to a sexual partner or to someone who uses their needle.

Carriers can look and feel perfectly well for a long time, maybe even the rest of their lives. Other people will develop a milder form of AIDS called the AIDS-related complex or ARC. ARC may go on for some time, it may go away, or it may turn into "full-blown" AIDS. The symptoms for ARC are the same as those for AIDS only not as severe.

What About Women?

Women account for 7% of all AIDS cases in the United States. This number is small but it is growing.

Women most at risk of getting AIDS are needle-sharing drug users. Next are women who are the sexual partners of men in high risk groups. Women who have had more than one sex partner during the last few years are also at risk because of the long incubation period.

The number of children getting AIDS from their mothers is also a concern. Scientists think the disease is passed from mother to infant in the womb, at birth, or maybe while breastfeeding.

Not every child of an infected mother gets AIDS. But it is easier for infants to get the disease because their immune systems are not as developed as adults.

Women need to take precautions to help prevent the spread of AIDS. Since 1981, the number of cases has been doubling every 5-13 months. Since the possibility of a vaccine or cure is many years away, women need to understand AIDS in order to protect themselves and any children they may have.

Women at Risk

- Women who have used IV drugs
- Women who are or have been sex partners of IV drug users, bisexual men or men with hemophilia
- Women born where the virus is often passed through male-female sexual relations, especially Haiti and African countries
- Women with more than one sex partner over the past few years

What Are the Symptoms of AIDS?

Many of the symptoms of AIDS are like those of colds or stomach flu. The difference with AIDS is that the symptoms either keep coming back or don't go away at all.

If any of the symptoms listed **below go** on for a long time, you should **see a doctor**.

- Unexplained weight loss greater than 10 pounds
- Persistent fever and/or night sweats
- Diarrhea
- Chronic fatigue
- Swollen glands, usually in the neck, armpits or groin
- Unexplained dry cough
- Shortness of breath
- White spots or unusual blemishes on the tongue or mouth

AIDS Can Be Prevented

AIDS is spread by the exchange of body fluids. Women need to be very careful about the exchange of these fluids, especially during sex. Sexual activities that might tear vaginal or rectal tissues should also be avoided.

Women can reduce the risk of getting AIDS by practicing safe sex.

- Always use condoms for vaginal and anal sex.
- Know sex partners and ask them about their health.
- Limit the number of sex partners.
- If you use IV drugs, do not share needles. Use only sterile equipment.

Taking the Test

A test to show if a person has AIDS antibodies is available. (Antibodies are agents the body uses to fight disease.) Private physicians and most state and local health departments can give the test.

If antibodies are found in a person's blood it means that they've been exposed to the AIDS virus. It **does not mean** that a person has or will get AIDS. It also doesn't tell if a person is still infected. There is no way of knowing *if* or *when* persons shown to have AIDS antibodies will develop AIDS or ARC.

Some women should consider being tested for AIDS. If you belong to any of the high risk groups and are either pregnant or thinking about getting pregnant, the test will tell you if you've been exposed to the AIDS virus.

Women who have the test should also consider counseling so they can get up-to-date, accurate information on their test results. Counseling is available at local and state agencies. Anyone giving the test can refer you to professional counselors.

For further information contact: AIDS Hotline—(800) 342-AIDS. U.S. Public Health Service.

Written by Julia Chiapella
Graphic design by Elizabeth Warshaw

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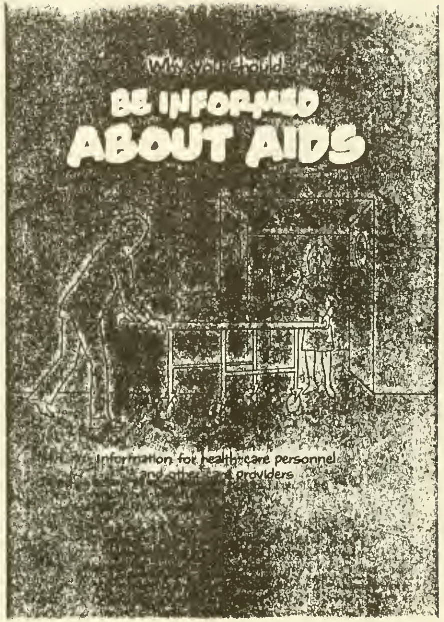


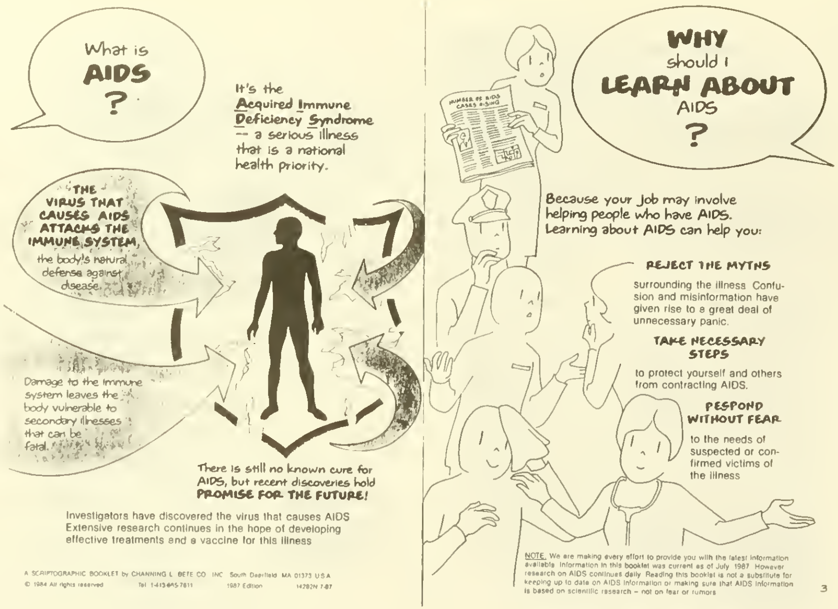
Why you should

BE INFORMED

ABOUT AIDS

Information for health-care personnel

and other care providers


NUMBER OF AIDS CASES RISING

What is **AIDS** ?

It's the Acquired Immune Deficiency Syndrome -- a serious illness that is a national health priority.

THE VIRUS THAT CAUSES AIDS ATTACKS THE IMMUNE SYSTEM, the body's natural defense against disease.

Damage to the immune system leaves the body vulnerable to secondary illnesses that can be fatal.

There is still no known cure for AIDS, but recent discoveries hold **PROMISE FOR THE FUTURE!**

Investigators have discovered the virus that causes AIDS Extensive research continues in the hope of developing effective treatments and a vaccine for this illness

A SCRIPTOGRAPHIC BOOKLET by CHANNING L BETE CO INC South Deerfield MA 01373 USA
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WHY should I **LEARN ABOUT** AIDS **?**

Because your Job may involve helping people who have AIDS. Learning about AIDS can help you:

REJECT THE MYTHS

surrounding the illness Confusion and misinformation have given rise to a great deal of unnecessary panic.

TAKE NECESSARY STEPS

to protect yourself and others from contracting AIDS.

RESPOND WITHOUT FEAR

to the needs of suspected or confirmed victims of the illness

NOTE. We are making every effort to provide you with the latest information available Information in this booklet was current as of July 1987 However research on AIDS continues daily Reading this booklet is not a substitute for keeping up to date on AIDS information or making sure that AIDS information is based on scientific research – not on fear or rumors

3

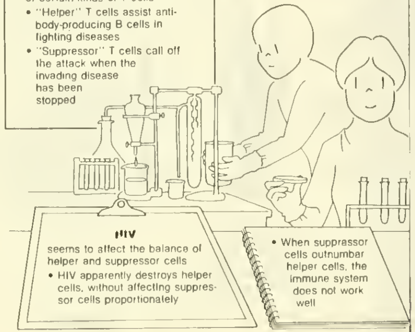
What CAUSES AIDS ?

Researchers have isolated and identified the cause -- a virus called HIV. (Human Immunodeficiency Virus).

A HEALTHY IMMUNE SYSTEM

includes special kinds of white blood cells called B cells and T cells, and depends on a balance of certain kinds of T cells

- "Helper" T cells assist antibody-producing B cells in fighting diseases
- "Suppressor" T cells call off the attack when the invading disease has been stopped



HIV

seems to affect the balance of helper and suppressor cells

- HIV apparently destroys helper cells, without affecting suppressor cells proportionately

- When suppressor cells outnumber helper cells, the immune system does not work well

EFFECTS ON THE BODY

HIV may be present in the body from a few months to 7 years or longer before there are any signs of illness. As HIV weakens the immune system:

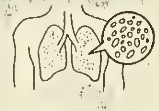
SYMPTOMS MAY APPEAR

People infected with HIV may experience symptoms, such as:

- swollen lymph glands in the neck, underarm or groin area
- recurrent fever, including "night sweats"
- rapid weight loss for no apparent reason
- constant fatigue
- diarrhea and diminished appetite
- white spots or unusual blemishes in the mouth.

OTHER ILLNESSES MAY OCCUR

People infected with HIV who go on to develop AIDS are unable to fight off a number of serious illnesses. One common illness of this type is *Pneumocystis carinii* pneumonia – a rare parasitic infection of the lungs, symptoms of which are fever, cough, and shortness of breath.



Scientific research shows that HIV may also attack the nervous system, causing damage to the brain and spinal cord. Signs of damage may include memory loss, indifference, inability to make decisions, partial paralysis, loss of coordination, and other problems in controlling the body

Researchers have developed a test to detect antibodies to HIV in the blood. The test, which is being used to screen donated blood, shows if a person has ever been infected by the virus. It does not indicate that a person has AIDS or will necessarily develop AIDS.*

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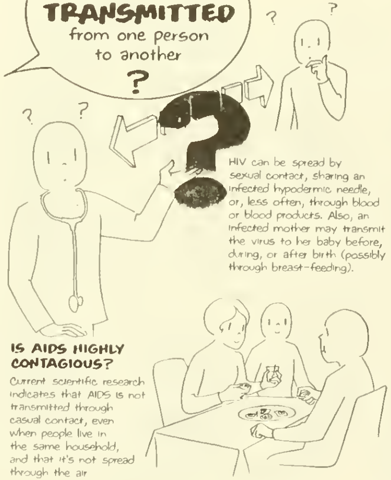
* If you think you've been exposed to HIV, consult your physician or your state or local health department to arrange for an antibody test – don't donate blood in order to be tested

HOW is the virus that causes AIDS TRANSMITTED from one person to another ?



HIV can be spread by sexual contact, sharing an infected hypodermic needle, or, less often, through blood or blood products. Also, an infected mother may transmit the virus to her baby before, during, or after birth (possibly through breast-feeding).

IS AIDS HIGHLY CONTAGIOUS?

Current scientific research indicates that AIDS is not transmitted through casual contact, even when people live in the same household, and that it's not spread through the air

WHO GETS AIDS?

66% ARE HOMOSEXUAL AND BISEXUAL MEN	who risk contracting AIDS through sexual activity. Especially at risk are those with many sexual partners.
17% ARE INTRAVENOUS DRUG ABUSERS	who may have been exposed to the illness by sharing contaminated needles.
8% ARE HOMOSEXUAL AND BISEXUAL MEN WHO ABUSE IV DRUGS	and risk contracting AIDS through sexual activity and drug use
4% ARE HETEROSEXUALS	who have been sexual partners of AIDS patients or other persons at risk of getting AIDS
3% ARE HEMOPHILIACS	and others who may have contracted AIDS through the use of donated blood and blood products

A small number of adult and adolescent cases don't fit into these groups. Other cases have occurred among children who have been given blood or blood products, or who may have contracted AIDS from an infected mother (see p. 6).

NOTE:

A few health-care workers, who are members of high-risk groups or who failed to follow recommended safety procedures to prevent contact with infected blood or body fluids, have developed antibodies to the virus that causes AIDS

PRECAUTIONS FOR HEALTH-CARE and LAB PERSONNEL

Practicing good infection control is the key to protecting yourself and others from contracting AIDS.

All personnel should follow these general guidelines:

DON'T MAKE ASSUMPTIONS

about who is infected Take necessary precautions with the body fluids of all patiants.

AVOID DIRECT CONTACT OF YOUR SKIN

and mucous membranes with the blood, blood products, secrations, wastes and tissues of all patients

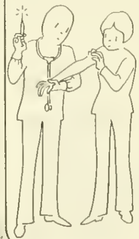
STAY INFORMED

about your health-care facility's policias Follow all recommended procedures exactly New discovaries about AIDS may mean changes in precautions necessary for your job

Also, follow specific recommendations from the Centers for Disease Control for your particular job.

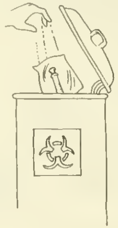
PREVENT WOUNDS

from sharp instruments and needles To avoid needle puncture injuries, nevar bend, recap or break needles by hand after use Place used needles in puncture-resistant containers



USE DISPOSABLE EQUIPMENT

whenever possible To reduce the risk of spreading AIDS, it's always wise to use needles, syringes and other equipment designed to be discarded after one use



PROTECT OPEN WOUNDS

from coming in contact with potentially infected materials Be sure to properly cover any broken skin surfaces

MORE SAFEGUARDS for health-care and lab workers

WEAR PROTECTIVE CLOTHING

If your job might expose you to patient's blood, secretions, wastes, etc. Gloves and gowns may be needed. Additional protective apparel, such as masks and goggles, may be needed for some procedures.

WASH HANDS THOROUGHLY

whenever you remove protective clothing and between every patient contact.

If your hands touch potentially contaminated blood, wash them immediately.

LABEL ALL SPECIMENS PROPERLY,

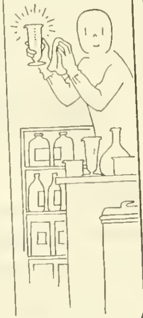
according to the policies at your health-care facility. If necessary, use a hospital-approved disinfectant to clean the outside of the container. Then, place the specimen in a leak-proof second container.

TAKE CARE OF CONTAMINATED ARTICLES

according to hospital policies for reprocessing or disposing of such items. Use specially designated plastic bags, labeling them in the same manner used for labeling specimens.

CLEAN UP ALL BLOOD SPILLS PROMPTLY,

using an approved disinfectant. Also, clean your work surface anytime it's contaminated by potentially infectious materials and after you've completed your work.



Recommendations for DENTAL PERSONNEL

Persons performing dental procedures or oral surgery should:

- Wear gloves, a mask and protective eyewear.
- Treat all instruments used in the mouth as potentially contaminated objects.

EYE-CARE PRACTITIONERS

To avoid possible exposure to the AIDS virus through an infected person's tears:

- Wash hands after each procedure and between patients.
- Wear disposable gloves if you have cuts, scratches or lesions on your hands.

Protective measures for
POSTMORTEM-CARE PROVIDERS

The mortality rate for people who have AIDS is high. Medical examiners, undertakers, embalmers, and morticians should:

ENSURE THAT IDENTIFICATION
of the deceased as an AIDS or suspected AIDS victim remains with the body until postmortem care is complete

WEAR ALL NECESSARY PROTECTIVE APPAREL
-- gloves, apron, mask goggles or glasses, shoe covering, etc -- to avoid skin or mucous membrane contact with contaminated materials

CLEAN WORK SURFACES,
floor, and instruments according to recommended procedures for hepatitis-B cases

WASH HANDS IMMEDIATELY
if blood contact occurs, and contact a physician for advice

DISPOSE OF ALL APRONS,
gloves, rags, towels, etc used during postmortem care, in the proper manner

NOTE. Communicable disease sanitation kits are available for morticians who must move a body from the place of death to a funeral home

---

Protective measures for
OTHER PROFESSIONALS

Contact with people who have AIDS or are infected with HIV is also a possibility for people who may be called upon to provide emergency care. These workers include:

- ☒ POLICE OFFICERS
- ☒ FIRE FIGHTERS
- ☒ PRISON PERSONNEL
- ☑ EMERGENCY MEDICAL TECHNICIANS

If you belong to one of these groups, you should:

KEEP IN MIND
that based on current research, HIV is not spread by routine contact, so that you can react calmly and rationally when helping someone who may have AIDS

TAKE PRECAUTIONS
when in contact with blood or other body fluids Wear gloves and keep disposable airway equipment or resuscitation bags available for emergency use

PRACTICE GOOD HYGIENE,
including washing your hands frequently (while on the job) and changing and washing uniforms daily – or whenever they become soiled

HOW LONG will these precautions be NECESSARY ?

That question can't be answered yet. But, many organizations are waging an all-out war on AIDS. For example, the U.S. Public Health Service is coordinating the efforts of:

THE CENTERS FOR DISEASE CONTROL

- which identified the illness, discovered patterns of occurrence, and is working with state and local health agencies to control AIDS

THE NATIONAL INSTITUTES OF HEALTH

- which is trying to find treatments and a preventive vaccine for AIDS

THE FOOD AND DRUG ADMINISTRATION

- which is working to help ensure the safety of blood and blood products for people who need them

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

- which is studying mental health aspects of AIDS

For more information about AIDS, call the toll-free U.S. Public Health Service hot line number, **800-342-AIDS.**

Soo-- PROGRESS AGAINST AIDS IS BEING MADE!

It's up to you to:

☑ **UNDERSTAND** what is known about AIDS.

☑ **TAKE** all necessary precautions for your job.

☑ **BE ALERT** to new developments in AIDS research.

Mr. WAXMAN. Yesterday, it was mistakenly stated that the Hotline tape refers callers automatically to Gay groups, including the one before us. The record will show that the Hotline is operated by the American Social Health Association, and that the materials given by that group are not the same those that were discussed yesterday.

Mr. DANNEMEYER. Mr. Chairman, may I comment on that?

Mr. WAXMAN. The gentleman is recognized.

Mr. DANNEMEYER. The persons who brought this information to my office told me that the counselor at the American Social Health Association gave the phone number for the Gay Men's Health Center. I may have misspoken with respect to that phone number for the Gay Men's Health Center being on the tape itself.

But the counselor working at the American Social Health Association is the one who gave the telephone number for the Gay Men's Health Center; and, candidly, I don't think we should tolerate that.

Mr. WAXMAN. Was that given on request to the individual calling?

Mr. DANNEMEYER. I don't know how else it would be given out.

Mr. MCKINNEY. Mr. Chairman.

Mr. WAXMAN. Yes, Dr. McKinney?

Mr. MCKINNEY. I think that it is very likely that that could be, if the caller were looking for an agency that provides direct client services. It is well known that Gay Men's Health Crisis is the only such agency in the city of New York.

It would be a very responsible reply to refer.

Mr. WAXMAN. You're not called the Gay Men's Health Center?

Mr. MCKINNEY. The Gay Men's Health Crisis.

Mr. WAXMAN. Mr. Dannemeyer has referred to the Gay Men's Health Center. Do you know whether that is the same organization?

Mr. DANNEMEYER. We believe it is the same organization.

Mr. WAXMAN. You believe that it is the same organization. Where did you get this information?

Mr. DANNEMEYER. A man named Duane Crumb, who identified himself as a Christian minister, was given the number for the Gay Men's Health Crisis Center. That organization sent him the literature that I have introduced for the record.

The counselor for the American Social Health Association was the one who gave Duane Crumb the telephone number that I have described.

Mr. WAXMAN. First of all, the question came up yesterday about the transcript for the recording. Whatever transcript you have is not the transcript from the recording. It is a transcript that individual made of the conversation. Is that correct?

Mr. DANNEMEYER. We have another witness, unsolicited, who brought this information to my office, that we have a recording of the conversation that took place.

Mr. WAXMAN. It's a recording of the conversation, but not a recording of the tape?

Mr. DANNEMEYER. The recording that we have is not of the tape. It is of the conversation that took place.

Mr. WAXMAN. The National Gay——

Mr. DANNEMEYER. This is a transcript of the National Gay and Lesbian Crisis Line.

Mr. WAXMAN. Are you familiar with that organization?

Mr. MCKINNEY. Yes.

Mr. SWEENEY. Yes, we are.

Mr. WAXMAN. Who are they?

Mr. SWEENEY. They are an agency in New York City that runs a national 800 number to respond to questions about Gay and Lesbian issues, as well as different AIDS issues.

Mr. WAXMAN. Do you know whether they are Federally funded?

Mr. SWEENEY. I do not believe they are Federally funded.

Mr. WAXMAN. Would someone be referred to them if they called the original hotline number, and asked for services for a Gay individual?

Mr. SWEENEY. It is quite likely that if an individual called and said I am a Gay person, I would like to get services or educational information because I am Gay, that they would be referred to that number. I think that is an appropriate referral, if asked for.

Mr. WAXMAN. Let me see if I can understand. We have the American Social Health Association that has received some Government funds to have a hotline. That organization, if they are requested for a referral for purposes of a Gay individual to talk to someone, do you know whether they would give out your phone number, or this other organization's phone number?

Mr. SWEENEY. Sir, I would hope that they would give out our phone number if a Gay person asks for it. We receive between 5,000 and 7,000 on our hotline every month.

Mr. WAXMAN. As I understand what Mr. Dannemeyer has is, someone made a transcript of a conversation with a Gay organization, and that is the transcript you want to put in the record?

Mr. DANNEMEYER. No. I don't want to put this transcript in the record, Mr. Chairman.

Mr. WAXMAN. You don't want to put that in the record?

Mr. DANNEMEYER. What I have asked to be placed in the record was the literature that——

Mr. WAXMAN. I understand. But yesterday, you seemed to indicate that what you found offensive was being said by the American Social Health Association.

Mr. DANNEMEYER. That is still my position. It think it is offensive for the American Social Health Association, using taxpayers' money, to be giving out the telephone number of the Gay Men's Health Center. I——

Mr. WAXMAN. Even when asked for information for a Gay person to contact an organization?

Mr. DANNEMEYER. That's where the stories differ. The person who brought this information to my attention identified himself as a Christian minister, not as a Gay person. The person working at the American Social Health Association gave the telephone number to this person who identified himself as a Christian minister of the Gay Men's Health Center.

Mr. WAXMAN. I don't know where they would refer Christian ministers to, but that was not the appropriate place to refer him. I just wanted all this on the record so people understood what transcripts, where, and whatever, belong to what organization.

I am going to take a short recess. Thank you very much for your testimony. We are going to take a short recess now before calling our concluding panel. We hope to reconvene in the next 5 minutes.

[Brief recess.]

Mr. WALGREN [[presiding.] Let me call us back to order and wake everybody up from that short hiatus.

The last panel today in this hearing is made up of Dr. Irving Weissman, a professor of pathology at Stanford University and a member of the Steering Committee on AIDS of the National Academy of Sciences, and Dr. Lawrence Corey, the Director of the AIDS Treatment Unit and a professor of medicine at the University of Washington, and Michael Callen, Community Research Initiative and a founding member of the People With AIDS Coalition of New York.

We want to welcome you to the committee and apologize for the interruptive nature of our process here, but that is the way it is and it is an imperfect process that we have. Your contribution to the record is very important to all of us.

With that let's go through the panel in the order in which I introduced you, and I am sure you picked up the ground rules from the previous witnesses. If you would limit yourself to something in the range of 5 minutes and summarize however you feel comfortable, focusing on the points that you really believe deserve to be underscored, we would be happy to have your testimony.

Dr. Weissman.

STATEMENTS OF IRVING L. WEISSMAN, PROFESSOR OF PATHOLOGY, STANFORD UNIVERSITY, MEMBER OF STEERING COMMITTEE ON AIDS, NATIONAL ACADEMY OF SCIENCES; LAWRENCE COREY, DIRECTOR, AIDS TREATMENT EVALUATION PROGRAM AND PROFESSOR OF MEDICINE, UNIVERSITY OF WASHINGTON; AND MICHAEL CALLEN, COMMUNITY RESEARCH INITIATIVE, PEOPLE WITH AIDS COALITION, INC.

Mr. WEISSMAN. I am Dr. Irv Weissman. I have been on the faculty at Stanford University for nearly 10 years, and I have been an immunologist for 20 years. I was on the Steering Panel and wrote the background paper on the pathogenesis of AIDS for that committee which produced the document that I think all of you have called "Confronting AIDS."

What I really want to say as briefly as I can is that despite some very major advances in understanding the isolation and the nature of the virus and the genetics of the virus that causes the disease and some very striking clinical advances in at least describing what happens to AIDS patients, that we still have some very major problems that are not being addressed appropriately.

The first point I want to make is that we do not yet have a sufficient knowledge base to develop an understanding which could lead to the development of vaccines, therapy for those people who have the disease already, effective therapy, prevention and other kinds of treatment, and we are not acting, I believe, appropriately to obtain that knowledge base.

The second point is that we have not yet even begun to recruit the best minds and laboratories in fields that are certainly directly related to AIDS, and there are very good reasons why we haven't done so. Most of the reasons, I think, are funding reasons, and some of them are structural: that is, how the structure of the funding agencies works.

Now, before I go too far into this, I would like to say that the second point I made, that is, the lack of the very best minds, is not just an invention of my own. A number of scientists, myself included, went back over the 20 best names, the 20 finest scientists in T cell biology alone, which is, of course, an area directly related to AIDS, and asked how many of those people who were so prominent in 1982 are now doing AIDS or AIDS-related research or research funded under the AIDS rubric? Very few of them are doing so.

So there is a problem that we have not developed a structure, a funding strategy that attracts and recruits the very best minds we have. It would be like setting up a Manhattan Project with two or three really good people, fantastic people, but without tapping the resources the country has to offer.

So let me move to my recommendations before I ramble much further, and then I will get back to the reasons why I think these are so. My first recommendation is that all AIDS research funding should be incremental to already established NIH funding levels plus inflationary increases backdated to 1982. I will show you documentation a little bit later that in fact there has been a recommitment of funds to research which has greatly damaged our ability to develop the sufficient knowledge base.

Second is that fundings for AIDS research should be broadly defined and certainly should include those areas of fundamental immunobiology, virology, lymphocyte biology, developmental biology and neurobiology which could provide the knowledge base for future advances in AIDS research. Most of this broadened funding, I believe, should be by independent investigator-initiated grants, not through the contract route.

Third, that construction and renovation costs should be added into the AIDS research budget, and the goal of such construction is first to provide safe containment areas for investigations with HIV, with HIV variants and with animals infected with HIV and HIV variants; second, to provide structural centers using high cost, high tech equipment to study the structures of the HIV molecules, also of those molecules on T lymphocytes which are utilized for infection by the AIDS virus, and of those molecules that T cells recognize on infected cells so that they can wipe out the seat of infection.

Third, to upgrade and extend the breeding, genetic definition and high containment facilities for animals involved in animal models of AIDS, particularly simian and rodent species. The fourth point is to establish research fellowships and research training programs at the undergraduate, the graduate, the M.D.-Ph.D., the post-doctoral and the post-clinical training levels with sufficient slots and competitive salaries to attract the best young minds in America into AIDS and AIDS-related research.

Already?

Mr. Walgren. That is all right. We have time to be flexible.

Mr. Weissman. So now I will just try to go briefly through a couple of the arguments before my 5 minutes is up.

Why do we have this paradox that we have this incredible epidemic, we have funds coming in for research, and yet we are not attracting the very best labs and the very best minds into this field? The first barrier, I guess, is containment facilities. That is, a number of scientists, myself included, would very much like to do AIDS research. We would like to do it the way that we can do it. That is, we would like to do it by developing animal models or working in the closest animal models available, or working even in tissue culture with the AIDS virus, but you have to have a safe containment facility.

At Stanford University and, I am sure, at many other institutions, those facilities simply are not available. When I approached our dean about developing such a facility, he said: Fine, you find the space, the building, and then the money to build it, and I will agree we should have that facility as a general use facility.

As you know, the NIH does not have funds for construction or renovation. If we are going to work with this virus, we have to work under safe conditions. If we are going to make an animal model of it, we have to have high containment facilities for animals. This is an incredible barrier for people to move into this area of research. We can't work with it safely.

The second point is to develop an animal model is going to be expensive and it requires really high class animal facilities. You could get an animal model that is close to relevant, that is, either a simian model, where you have genetically-defined strains of monkeys so that you could transfer cells from one animal to another to see what the course of the disease is, to ask, for example, what is the mechanism for infection when the semen contains the virus, is it in the seminal fluid, is it free virus, is it an infected cell, is it a sperm? We don't know those answers yet.

Once it gets into the animal, how does the virus spread from one cell or one tissue to another? How does it get rid of all those T lymphocytes that normally protect against infection? We don't know, and we cannot invade the human body to find it out. We have to have an animal model for that, and that takes money and takes time and takes people. So on and so on. We don't know yet how to identify those cells which could usually eliminate the virus infection but in this case they don't.

So there are tremendous needs to develop these kinds of models, and the brightest people would follow if the models were developed.

Now, in the funding for AIDS research from 1982 to 1986, you have a document that was cited in this AIDS thing that was written by Richard Krause, who was the former head of National Institutes of Allergy and Infectious Disease, which shows that the funding for AIDS at the NIH has largely been recommitted out of the already existing NIH budget, and very little add-on funds came about.

AIDS is an add-on disease, quite clearly. It was not around, at least that we could see, as a clinical entity probably before 1978. It is an add-on research burden, yet there is very little add-on research money. Now, when NIAID or NCI, the institutes that mainly fund for AIDS research, had to develop these funds, they took it away from something else. What did they take it away from? Basic immunobiology, T cell biology, virology, neurobiology, just exactly the areas that we must learn more about in order to develop the knowledge base, in order to develop the diagnostics, the therapeutics, transplantation, whatever we are going to need to be able to take care of those people who already have the disease, and, of course, to prevent the disease from spreading.

In addition, there are some areas of research which deal with solving structures at a very, very microscopic level that require very high cost facilities, called x ray crystallographic facilities. There are a few tiny laboratories around the country and very little training money for people to go into this area; yet, it has proved crucial for our understanding how particular viruses can cause infection, how particular viruses can get rid of T cells, and in fact, how T cells can recognize an infected cell and tell it apart from a free virus or from a normal cell.

Solving that question isn't trivial. Solving that question is central to try to develop rational vaccines and rational therapies. So we have to have some way of developing both training grants and facilities for x ray crystallography at a number of places.

I can see my time must be getting short, so I think I will just close there and take any questions.

[The prepared statement of Mr. Weissman follows:]

Statement of Irving L. Weissman, M.D.

AIDS and ARC are human diseases caused by a retrovirus called HIV. A remarkedly intense and effective collection of research efforts at both the basic science and the clinical science levels have led to the isolation of the virus, the definition of its genetic structure, the demonstration that it is associated with each of the disease complexes occurring in AIDS patients, and especially that the virus appears to attack and cause the elimination of a critical subset of protective cells in the body—the CD4 T lymphocytes. The result of this depletion of most CD4 T lymphocytes is an unusual susceptibility to infection by foreign invaders that are usually easily eliminated. Because so much has been learned about the virus and the diseases it causes it is tempting to believe that we have sufficient knowledge to combat this epidemic at a scientific level; and that as a result of that focused combat we have an excellent chance to develop drugs to treat patients with the disease, to develop other drugs designed to restore the immune system in such patients, and to develop vaccines that will prevent populations from being infected by HIV. The major thesis of this document is that these assumptions are not true, and that we do not have a sufficient knowledge base yet to guarantee an expeditious and appropriate set of responses leading to the development of necessary vaccines, drugs, diagnostic, and therapeutic agents. Furthermore, one might assume that the great need to combat this epidemic would have resulted in the recruitment of the very best minds in immunology, virology, clinical infectious disease, developmental biology, and neurobiology to work on AIDS and the diseases it engenders. That is not so. While the research carried out to date includes much which has been of the highest quality, nowhere near the enormous talent pool available to work on this disease has in fact been effectively recruited. Thus there are very major barriers to completion of research adequate to stem the AIDS epidemic, both at the level of developing an appropriate knowledge base, and recruiting the talent necessary to develop that knowledge base. In this document I shall try to explain what those barriers are and how I think they can be breached.

AIDS appears to be a new human disease, and as such it is an "add-on" to the Nation's health research agenda. We now have a strong national mandate to increase funding in all areas which might lead to an understanding of the AIDS virus infection, and the systems which it attacks, yet the current AIDS—research funding is not add-on. In fact, funds have largely been recommitted away from areas of research in basic immunobiology, developmental biology, virology, cancer biology, and T lymphocyte biology, and instead these funds have been committed to the urgent research on the AIDS viruses and the patients who have the disease. Thus we are in a funding mode which paradoxically must slow down the development of a fundamental understanding necessary to develop a knowledge base sufficient to respond to the challenge of the disease.

How did this paradox come about? To illustrate the problem I shall use one example, although it is not limited to the Agency I cite. The National Institute of Allergy and Infectious Disease (NIAID) has had a major responsibility in developing and carrying-out AIDS related research. That responsibility came from mandated funding from both the legislative and executive branches of the U.S. Government. The amount mandated was not fully incremental to the budget of NIAID, and therefore funds had to be taken away from other portions of the NIAID budget. Just prior to this mandate the majority of research funds distributed by NIAID went to investigator-initiated grants (RO1 and PO1 grants) in laboratories mainly in academic settings and research institutes that are primarily staffed with graduate students, medical students, and postdoctoral fellows. In fact, historically, the development of new and useful fundamental knowledge in the areas of basic medical sciences has traditionally come primarily from these investigator-initiated grants. The investigator-initiated grants represent the most important "cottage industries" for science, where each scientist develops his or her own hypotheses about what might be going on in the field, develops experimental models for testing these hypotheses, and submits a grant which, if funded, should approach the experimental questions over a 3–7 year period of research. These RO1 grants are reviewed by panels of independent scientists, almost all of whom are not employees of the government, who rank them for originality and scientific merit; ranked grants are then funded pretty much according to their order of merit.

Each of the NIH institutes also funds intramural programs, mainly on the Bethesda campus, as well as having the power to grant contracts on specific research or development areas which they deem most important. The intramural NIH programs are very much like the RO1 programs, although they do not face the same type of independent review as the RO1 grants. In contrast to the investigator-initiated grants the contract programs are initiated without a requirements for broad-based review. The contract programs therefore depend for their success on the wisdom and breadth of the NIH administrators to develop the project areas, to publicize their availability, and to select the successful contracts. during the past 5 years the NIAID intramural and contract programs have risen to be the major recipients of funding, at the expense of the RO1 grants.

Even for those RO1 grants which are funded, for the past several years grants not classified by NIAID officers to be related directly to AIDS research have been under severe funding cutbacks, averaging 5–15 percent per year rather than the actual 10–20 percent inflation for personnel and materials. The types of research not classified under the AIDS rubric, to name a few, include many fundamental studies in animal models of virus infections; molecular genetic research of several related virus types; the fundamental aspects of T cell development, including the origin and life history of CD4 T lymphocytes, and the kinds of T cells which carry out anti-viral immunity in ways which wall off or eliminate virus-infected cells; research involving isolating and crystallizing the envelope proteins from members of the retrovirus family to understand their structures, a prerequisite to defining how these viruses attach to and destroy CD4 T cells; the isolation and crystallography of the CD4 proteins; and the basic studies of the footprints viruses leave on the surface of infected target cells which allow immune T cells and other killer cells to recognize and destroy those virus infected cells.

Although one might think that shifting these funds from RO1 grants to contracts might lead the best of the independent external investigators to respond to requests for funding under NIAID contracts, in fact this is usually not the case. Most highly intelligent and accomplished investigators do not wish to surrogate their own ideas and projects to those dictated and administered by other scientists (most of whom may not be as bright or as accomplished as the external investigator). Thus on the basis of funding alone, most NIH institutes have not been successful in attracting outstanding and accomplished investigators to commit themselves to a long-term research program related to AIDS, or to developing the fundamental knowledge base important for AIDS research.

The best people working in external research labs are bright young students who are beginning 1) undergraduate research experiences, 2) graduate studies in the biomedical sciences, and 3) postdoctoral research training prior to obtaining a research or academic appointment. Unfortunately, the trend in Public Health Service and National Science Foundation funding for the past several years, and acutely in the past year, is to limit or decrease numbers of fellowships for undergraduates, graduate students, M.D.-Ph.D. students, and postdoctoral fellows.

To summarize, while the increased funding for NIH intramural programs has paid off spectacularly in AIDS molecular virological and immunological research, these precious few laboratories cannot develop the required knowledge base on their own. The net affect of an AIDS funding mandate has therefore been a very significant shift in PHS funding away from external investigator-initiated grants and to NIH intramural and NIH directed contracts, neither of which involve broad-based peer review. As a result the payline for external investigator-initiated grants in some of these crucial areas has become even more stringent, resulting in a dampening rather than an expansion of first-rate investigation and training. While it is clear to most members of the NAS/IOM panel that our commitment to fight the AIDS epidemic will require prolonged and intense research, these actions will deny creation of a long-lasting infrastructure necessary to develop the understanding of the normal physiology of those parts of the body attacked by the AIDS virus, and for understanding how AIDS and AIDS-related viruses are involved in the pathogenesis of AIDS.

AIDS so far is a human disease, and much of what we know about the events that occur from the moment of contact with the virus to the time the patient reaches terminal stages of his or her illness in the hospital is fragmentary at best. Hospital care and autopsy analyses have taught us much about terminal stages of the disease, yet we do not yet know 1) the mechanism(s) by which the AIDS virus is transmitted from one person's cells to another person's cells; 2) the events that occur that spread the infection from one part of the body to the next; 3) the events that lead to a successful antibody response to certain parts of the virus, but an unsuccessful T cell-mediated elimination of the virus-infected cells; and 4) whether the virus eliminates the CD4 T cells during their development in the bone marrow and the thymus directly, or by some indirect means. In fact, published research shows that although over 99 percent of the CD4 T cells are eliminated during the course of HIV infection leading to AIDS, at no time can the virus be found to be produced by more than a rare subset of CD4 T cells (the highest estimates I have seen are still less than 1 in 10,000 of these cells). Because there are appropriately very important medical and ethical safeguards against unwarranted invasion of the human body to find answers to some of these questions it is likely that we shall continue to be largely ignorant about the full extent of the introduction, spread, and pathogenic consequences of HIV infection throughout the course of human disease. Even if it was possible to obtain rapid, complete, and sterile autopsies on HIV-infected individuals who die of other causes (for example, accident, suicide, myocardial infraction), the limitations on such research will not lead to the answers we need to have.

Naturally occurring retroviral infections leading to significant acquired immunodeficiencies have been found in several vertebrate species. Although only a few potentially produce a syndrome quite similar to human AIDS, none has been studied sufficiently to elucidate the mechanisms of pathogenesis, so that one could know whether the different types of the immune deficiency result from similar or different basic mechanisms. Simian AIDS and simian retroviruses are perhaps the most relevant potential examples. It is conceivable that a large scale effort on simian AIDS could be developed which would allow one to develop genetically defined monkeys which would allow the transfer of immune rejection of virus-infected cells from one individual to the other, therefore allowing scientists to work out questions of the spread of the infection and the host immune response to it. Despite the emergency of knowledge of these important models, actual NIH funding for examples such as simian AIDS decreased for the several years leading up to 1986.

A completely analogous animal model of HIV-induced human AIDS has not yet been found. Most of what has been learned about fundamental aspects of animal virology, immunology, lymphocyte biology, and to a lesser extent neurobiology has come from extensive investigations with genetically defined inbred strains of rodents. In these times of recombinant DNA manipulations of retroviruses and tissue culture cells and of transgenic mouse strains, it is possible that a completely analogous animal model of HIV-induced human diseases might be developed. The result of such a development would be the rapid entry of a large number of first-rate scientists at a number of levels into the AIDS field.

HIV is a human pathogen, and its study requires high-containment facilities. The lack of such facilities is a barrier for many first-class scientists to enter the field. In the future, if HIV-infected animal models are developed, high-containment animal facilities will be required to guarantee safety and the full participation of the wider scientific community in AIDS research.

For example, at Stanford University and Stanford Medical School (and probably elsewhere) there is no HIV containment facility available to qualified investigators who wish to follow their own lines of inquiry; and no fully developed high containment animal facility to house mice or other animals of an important animal model; and no funds to build such facilities for common use by qualified investigators. Furthermore, due to the repeated funding restrictions from NIH on purchase of new and high cost equipment many laboratories are still working with instruments such as ultracentrifuges which are 10–20 years old. Finally, there is no NIH funding available for construction of new or renovation of old laboratories. Thus many outstanding laboratory groups continue to work in overcrowded and underequipped facilities. High cost special new facilities such as those required to do modern structure analysis by x ray crystallography and related technologies do not exist at many academic and research campuses, and NIH moneys required to develop these facilities are not easily obtainable.

Recommendations:

1. All AIDS research funding should be incremental to already established NIH funding levels plus inflationary increases back-dated to 1982.

2. Funding for AIDS research should be broadly defined, and certainly should include those areas of fundamental immunobiology, virology, lymphocyte biology, developmental biology, and neurobiology which could provide the knowledge base for future advances in AIDS research. Most of this broadened funding should be via independent investigator-initiated RO1 or PO1 grants.

3. Construction and renovation costs should be added into the AIDS research budget, and the goal of such construction is first to provide safe containment areas for investigations with HIV, with HIV variants, and with animals infected with HIV and HIV variants; second, to provide multiple structural centers using high cost, high tech equipment to study the structures of HIV molecules, of molecules on T lymphocytes utilized for infection, and of molecules used for targets of immune attack against HIV infected cells; third, to upgrade and extend breeding, genetic definition, and high containment facilities for animals involved in animals models of AIDS, particularly simian and rodent species.

4. Establish research fellowships and research training programs at the undergraduate, the graduate, the M.D.-Ph.D., and the postdoctoral and postclinical training levels with sufficient slots and competitive salaries to attract the best young minds in America into AIDS and AIDS related research.

[Note: This document is derived from a background paper by the author written for the National Academy of Sciences/National Institute of Medicine panel on AIDS which carried out a study in 1986, culminating in a report released in October of 1986. The author of this document wrote the background paper entitled Pathogenesis of AIDS for the Committee, on which he served as both a member of the steering committee and a member of the panel. Because the research for the report was completed by May, 1986, this document could be inaccurate on some non-scientific issues relating to funding subsequent to October, 1986.]

Mr. WALGREN. We appreciate that testimony and we are pleased to give you the flexibility to add to it, either as we close or even in after-thought by writing.

There are some more bells that are ringing. Why don't I just go over there and vote and come right back, and this will take us about 5 minutes, and then we will be able to turn to the balance of the witnesses. I apologize for that, but we have no control over it. Be right back.

[Brief recess.]

Mr. WALGREN. Let's go back on the record and turn to Dr. Corey. Dr. Corey.

STATEMENT OF LAWRENCE COREY

Dr. COREY. Thank you, Mr. Walgren.

It gives me pleasure to address you today concerning my and many of my colleagues' perception of some of our country's immediate research needs.

I come to you in my role as Director of the University of Washington's AIDS treatment program, as a physician who has been a researcher, medical educator and patient care advocate of persons with viral sexually transmitted disease for over 12 years, as a professor of medicine who leads a research group in the AIDS treatment, is associated sexually acquired cofactors, and as the director of one of the few training programs in viral sexually transmitted diseases in the United States.

The charge of your committee concerning our country's needs for solving this problem are extensive and many qualified persons have already addressed you. I am not going to minimize any of the importance of others' perceptions and concerns but will limit myself to a rather focused area, the necessity of providing facilities to perform clinical research for what we term secondary prevention of AIDS: that is, stopping the development of AIDS in those who have infection with the human immunodeficiency virus.

By way of background, I think everyone realizes, and Dr. Silverman has gone through this, that the agent that causes AIDS is a formidable opponent in that the AIDS epidemic or what should more appropriately be called the epidemic of HIV infection in viral sexually transmitted infections that we are experiencing in the United States will not be amenable to a quick fix. To develop the biological know-how on how this virus persists in the human host for an extended period of time and what are the host immune responses that provide protection will, to adapt a phrase, take our best and brightest.

These pieces of information are necessary if we are to develop a vaccine. To develop better therapies to slow down what appears to be a nearly inevitable progression of this infection will also take a concerted research effort involving scientists in nearly every conceivable discipline. The data that indicates that after 7 years, nearly 30 percent of those infected with HIV develop AIDS, an additional 25 percent of symptomatic illness spurs those of us who are involved in research toward the development of new therapies with an almost nightmarish urgency.

However, despite our resoluteness concerning this task and our willingness to devote 80- to 100-hour workweeks to achieve this goal, we also are frustrated by the lack of facilities to accomplish this charge. I applaud the committee's insight in authorizing regional AIDS research centers; however, the nature and amount of money available to these centers is inadequate.

Capital construction for specialized laboratories and clinical facilities for AIDS patients and researchers is needed similar to the cancer research centers so successfully implemented about 15 years ago. It is not unusual—in fact, I find it common—to have many of the brightest of our graduate students or medical students come to us and ask to work in the area of AIDS research. They and I are willing to compete through the peer review system to obtain funding to conduct the experiments. The money and sometimes even the equipment to perform their experiments are often available.

What is not available, however, is the space to do the work. I am not talking about spaced used between 9 o'clock and 5 o'clock but space that is already occupied at night and on weekends. In the last year I have personally had five doctoral and post-doctoral persons with superb research training ask to participate in our treatment and vaccine-related research. All had to be referred elsewhere because of the lack of space. All are now working in other areas, lost to the AIDS research effort for years, if not forever.

In fact, recently I recalled one of these particularly excellent students who had previously approached me because we now had some money to fund her. She, however, was involved in another project with another organism and could not be persuaded to leave the bench for her work.

When we talk about space, as you have heard earlier, we are talking about P–3 or high containment laboratory space, the kind of laboratory space that is expensive to build and, frankly, is more space per person. You can not afford to have accidents in the laboratory when working with this virus, and we need these kinds of facilities. They are costly facilities. They are facilities that must be well staffed and cannot be crowded.

As a scientist, I am trained as more of an observer than a predictor; however, it is apparent to those of us working in the field that in the next 5 years we will be faced with the administration of antiviral drugs to a large spectrum of persons infected with the aids virus. The monitoring of these patients will require sophisticated virology and immunology laboratories. We will be faced with training primary care physicians in technologies of health care and experimental therapy that are new to them.

If we are to offer the latest available modalities of therapy to these persons, we must establish regional centers of excellence that possess the persons, the core laboratories and scientists to conduct these studies, to train health care personnel in the care of these patients and conduct the pioneering studies to extend the duration and quality of survival. Parenthetically, I would say having an effective drug that can be given to the asymptomatic seropositive persons will, I think, go a long way towards solving the "dilemma" of resistance to testing for HIV.

While there have been moneys appropriated for the conduct of these studies and even the establishment of regional centers, there has been none for the construction of the facilities in which to do the studies. The current problem is a longstanding one in which space for biomedical research has been inadequate for years. Renovation moneys will not solve this problem.

Frankly, it is not possible to proceed with the efficiency and pace which this problem deserves without the bricks and mortar to tackle the problem.

The model of the cancer center is, in my opinion, an excellent one and one which has been successful in bringing the latest available modalities of therapy to patients. I would envision at least 5 to 10 to even more regional clinical basic and research centers that would contain outpatient facilities for the conduct of clinical research, core virology and immunology laboratories needed for the support of these studies, and basic and clinical science laboratories to bring the bench scientists, the clinicians and patients. This approach will speed research and optimize care.

Specifically, I would even suspect that at least any facility would need approximately 40,000 square feet to house the appropriate facilities, and approximations are made in the testimony I have submitted. Without these types of centers, the time line to conduct clinical studies and to provide the latest available modalities of therapy to patients with this infection will not proceed with the pace and the expectations of the American public and its elected representatives.

I know there is at times resistance to the construction of buildings. However, the cancer research centers, such as the Dana Farber and the various other ones, Hutchinson Center in our city, are successful models of the bricks and mortar that save lives in cancer therapy. A similar approach is needed for HIV infections, centers that mold a cohesive group of basic clinical scientists, physicians, epidemiologists, educators and health care personnel trained in the prevention, and control and education of sexually transmitted diseases, persons interested and dedicated to as expeditious a solution to this disease as is humanly possible.

Thank you.

Mr. WALGREN. Thank you very much, Dr. Corey.

Mr. Callen.

STATEMENT OF MICHAEL CALLEN

Mr. CALLEN. Four years ago I was one of three people with AIDS to testify before Representative Ted Weiss' Subcommittee on Government Operations on the subject of the Federal response to AIDS. Anthony Ferrara and Roger Lyon have since died. I carry on their fight because they cannot.

Sometimes I feel like the Elie Wiesel of AIDS. I feel compelled to testify to the world about an almost unspeakable horror. With AIDS the task is not merely to remember those who have died; it is to prevent more death. Not everyone dies from AIDS and AIDS-related conditions, just mostly everyone.

When asked to speculate on why I am still standing, I usually joke: "Luck, Coca-Cola Classic and the love of a good man." One thing is for sure. My survival has nothing whatsoever to do with Federal treatment research efforts, and it is this problem of treatment research that I am here today to address.

I am sure you will understand why those of us with AIDS are impatient. We do not have time to wait for the research systems already in place to move at the glacial pace for which bureaucracies are famous. While I do not doubt the personal commitment of many NIH scientists, it is clear that the U.S. Government's track record in terms of treatments for AIDS is nothing short of scandalous.

More than 6 years into the AIDS crisis, we have fewer than 1,000 people enrolled in treatment trials in the AIDS treatment evaluation units. More distressing still is the paucity of compounds tested.

I would like to discuss an exciting development which might dramatically speed up finding treatments for this insidious disease. One of my main criticisms of Federal efforts derives from the fact that treatment research priorities are set almost entirely by academic, bureaucratic research scientists. The valuable insights of general practitioners who are dealing with the day-to-day patient management are undervalued or ignored. This is a waste of knowledge which we can ill afford.

In an attempt to mine this largely untapped resource, the People With AIDS Coalition in New York has formed the Community Research Initiative. CRI has been set up to permit community physicians to conduct treatment research in their own offices using their own patients. This should dramatically expand the number of people involved in treatment trials, which in turn will provide better answers faster.

Briefly, here is how CRI works. In the United States, all research involving human subjects must meet certain appropriately rigorous standards. A protocol must be written outlining precisely what is to be tested, how and why. This protocol must then be reviewed by a scientific advisory body. In addition, an institutional review board made up of community representatives must ensure that research subjects will not be exposed to unnecessary risk. Someone must also coordinate the enormous logistic details of recordkeeping, subject solicitation, coordination of appointments and procedures and the analysis of findings.

All of these functions necessary to conduct FDA-approved research are normally present only in medical centers or at Federal research institutions, but the one things medical centers lack is the subjects themselves. They are forced to advertise for subjects or to rely on referrals.

CRI proposes to bring the mountain to Mohammed, so to speak. Local physicians already have the patients. What they lack is the administrative structure to conduct trials in their own offices. The Community Research Initiative provides such a structure. There are several immediate advantages to this approach. One, while the ATEUs have some trouble filling trials, community physicians have large and willing patient populations from which to draw.

Two, since community physicians would be responsible for coordinating day-to-day care, they would be more likely than a medical center researcher to know all the medications that a patient is on. Many patients who participate in the AZT trials concealed the fact that they were on other medications during that trial. This may have hopelessly undercut the value of those trials. This problem would be reduced or eliminated if general practitioners could conduct research on their own patients. This would be an enormous advantage.

Three, the major asset boils down to this. Community physicians have the trust of their patients, a major advantage given the general level of suspicion which has surrounded Federal treatment efforts to date.

The final advantages are these. CRI can conduct FDA-approved research faster and cheaper and perhaps better than more traditional avenues, faster because the will to move quickly is there, cheaper because there is less overhead since doctors use their own offices to conduct the research, and perhaps better because a community with its back against the wall of AIDS will not permit anything but the highest quality of science to occur in its name. We can avoid the bureaucratic entrenchment and silly turf battles which I believe have plagued AIDS research treatment to date.

A founding principle of the People With AIDS self-empowerment movement is that people with AIDS ought to have a say in processes where decisions are being made which directly affect our lives. If treatment priorities must be set, they ought to reflect input from those of us most directly affected, people with AIDS.

Lest anyone fear that people with AIDS are unable to objectively and effectively participate in the design and execution of clinical trials, I hasten to point out that the scientific advisory body which currently reviews CRI protocols contains individuals of the highest scientific caliber, many of whom also review protocols for the ATEU's.

We have sought out and gained the support of many of the leading AIDS experts in this country. We are committed to conducting top notch research. Our lives deserve no less. CRI would complement, not compete with parallel Federal efforts.

It can be done. Creative solutions are necessary for these crisis times. American history is replete with examples of what this country can accomplish if it puts its mind to something.

I seek your support and welcome your questions. Thank you.

Mr. Walgren. Let me just ask for some short answers because these are second bells and it gives us just a couple of minutes and then I am going to have to go back over there. It only makes sense, I think, at that point to end.

Mr. Callen, one of the concerns in AIDS drug evaluations is the protection of human subjects from harm. Can you describe the precautions that your organization might take in protecting people from research risks? Is there anything you would like to add in that area that would be helpful for the record?

Mr. Callen. I am a member of the Institutional Review Board for the CRI, and I can tell you that we go over these issues in excruciating ethical detail. One example is we were approached to be involved in a trial of DDC, and a group from our Scientific Advisory Committee went up to the company and looked at the data and has rejected pursuing those trials further.

There are people in the lesbian and gay community, and particularly the AIDS community who are arguing that we should deregulate and that anybody should be able to take any substance they want. I am not of that view, nor is the Community Research Initiative. We believe that the regulatory system can work, that there need to be safeguards, and we would be committed to not pursuing any trial where the risks outweighed the potential benefits.

Mr. Walgren. Dr. Weissman, you indicate, and Dr. Corey as well, that we need these facilities, that these facilities will be substantial. Obviously, there can be only several of them. How would you place them at that point? Do you have any shorthand for the guidance of those who argue that these facilities should be placed by picking a city or picking an institution? How do you pick among the institutions if we don't have enough to go around? Is that a problem that you feel deserves to be addressed?

Mr. Weissman. I think that for high containment, P–3 facilities, they are expensive but not so expensive that each medical center cannot afford having one or more. I would suggest that they be funded through investigator-initiated grants, going before the usual kind of review body justifying their need to have that kind of facility at that school, and then take their chances with the peer review process.

For something that might be very special and very expensive, that is, developing high-containment primate facilities and very large breeding facilities for what we would call histocompatible or

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genetically defined monkey lines so that one could really do that important kind of research, obviously you can't do that everywhere.

Again, there are very fine primate centers at several places around the country that could carry this out if they had sufficient support.

Mr. WALGREN. Let me on behalf of the committee thank you all for being a resource to us, and particularly Mr. Callen for being a very special resource to us. We appreciate very much your reaching out to us in this process, and we appreciate each of you being a resource that we can reach back to.

I apologize for and I know Mr. Waxman would want me to express his apologies for the interruptions and the fact that he had to meet another commitment at the time your panel came up, but that doesn't mean that we appreciate you any less.

Thank you very much, and we will look forward to where we go from here.

[Whereupon, at 5:43 p.m., the hearing was adjourned.]

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